

Dangerous Medicines-The Facts

BANNED *and* BANNABLE DRUGS



4th Revised Edition

Prepared in Public Interest by



Voluntary Health Association of India

VOLUNTARY HEALTH ASSOCIATION OF INDIA (VHAI)

VHAI is a non profit making, non-government organisation, coordinating the health activities of over 3000 health institutions all over the country.

VHAI is committed to social justice in health care. This commitment is reflected in its training programmes and the production of educational material. VHAI is the biggest distributor of low cost relevant health education material in the Third World.

VHAI's involvement with the drug issue has been its response to the increasing commercialization and pharmaceuticalization of health care. VHAI has been deeply concerned about the increasing misuse of drugs, non-availability of essential drugs, non-availability of unbiased drug information and poor drug controls and legislation.

VHAI has for several years been endeavouring to ensure that India's National Drug Policy is rational and people oriented. It has also endeavoured to reach out to consumers and health personnel to make them more drug conscious. VHAI is part of the Health Action International Network of like-minded organizations across the world fighting for Rational Drug Use.

ALL INDIA DRUG ACTION NETWORK (AIDAN)

AIDAN consists of numerous health, consumer, legal aid and human rights organizations and people's science movements. It is a loose network of academicians, professionals, social activists, individuals and organizations who are deeply concerned about the drug issue and working towards the adoption and implementation of a people oriented Rational Drug Policy in India as a part of a People's Health Policy.

ALL INDIA DRUG ACTION NETWORK COORDINATING COMMITTEE

- (1) Academy of Young Scientists
- (2) Association for Consumer Action on Safety and Health (ACASH), Bombay.
- (3) Arogya Dakshata Mandal, Pune
- (4) Catholic Hospital Association of India, Hyderabad.
- (5) Community Development Medicinal Unit, West Bengal.
- (6) Consumer Education and Research Centre, Ahmedabad.
- (7) Consumer Guidance Society of India, Bombay.
- (8) Drug Action Forum-West Bengal, Calcutta.
- (9) Drug Action Forum-Karnataka, Bangalore.
- (10) Delhi Science Forum, Delhi.
- (11) Kerala Sashttra Sahitya Parishad, Kerala.
- (12) LOCOST, Baroda
- (13) Lok Vigyan Sanghatna, Pune.
- (14) Medico Friends Circle, Pune.
- (15) Voluntary Health Association of India, Delhi.

For those wishing to pool in their efforts towards ensuring rational drug use and appropriate responses in health care contact:

Dr. Mira Shiva, MD
Convenor, All India Drug Action Network
& Head of Division
Public Policy
Voluntary Health Association of India.

DANGEROUS AND USELESS MEDICINES - SOME FACTS

BANNED & BANNABLE DRUGS

Brought out in Public Interest

by

Dr. Mira Shiva MD
and
Dr. Wishvas Rane



VOLUNTARY HEALTH ASSOCIATION OF INDIA
40, Institutional Area
South of IIT
New Delhi 110016

The information contained in this book is compiled from various sources and every effort has been made to ensure its accuracy. However, we cannot take responsibility for any error or omissions made due to our having to depend on secondary sources also. It is extremely difficult to obtain authentic information easily from reliable sources and if there are any omissions it merely highlights the urgency and the need to ensure easy availability of unbiased information from official sources.

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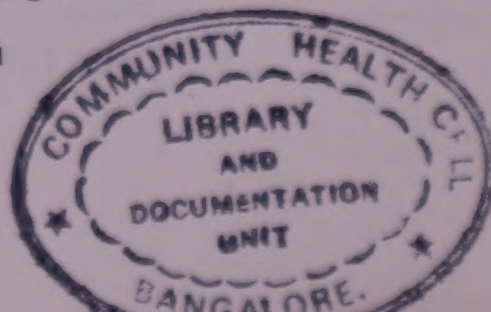
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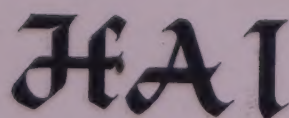
Fax: 011-6853708

Email—VHAI@unv.ernt.in

Composing and Page Making—Printexcel, 30-B, Ber Sarai, New Delhi.

Front Cover— Tamal Basu





Health Action International

H.A.I.-Europe
Jacob van Lennepkade 334 T,
1053 NJ Amsterdam,
The Netherlands

Tel : (+31 -20) 83.36.84

Fax: (+31 -20) 85.50.02

It is universally accepted that the pharmaceutical industry's first priority is to make a profit. This applies to both multinational and national companies in India.

Pharmaceutical business, like any other business, is about making money. It is towards this goal of making the most possible money that industry executives normally devote their energies day in and day out. This leads to a conflict of interest between the industry and the social, medical and economic needs of the country and the people to select and use drugs in the most rational way.

To reach a compromise and to safeguard the people, every country has to in place a very effective safety net - the Drug Regulatory Authority (DRA) supported by statutory advisory bodies.

The DRA has a moral duty to regularly review every drug in the market as to its safety, efficacy and quality and weed out those that are harmful. To help countries carry out this important exercise, the United Nations publishes a list of harmful drugs at regular intervals. Using this document several countries in Asia have taken appropriate actions to weed out dangerous drugs. But not the Indian DRA, which comes to have a dismal record in not banning dangerous drugs.

The Voluntary Health Association, supported by well-known experts from Universities and several socially-conscious voluntary groups, has carefully gone through the drugs in the Indian market and published a list of Banned and Bannable Drugs.

Dangerous drugs that have been banned many years ago in several countries, including neighbours in South Asia, are allowed to be manufactured and aggressively promoted in India. This poses a great danger to the health of the people in India.

VHAI is bring out a revised and updated version of the Banned and Bannable Drug List.

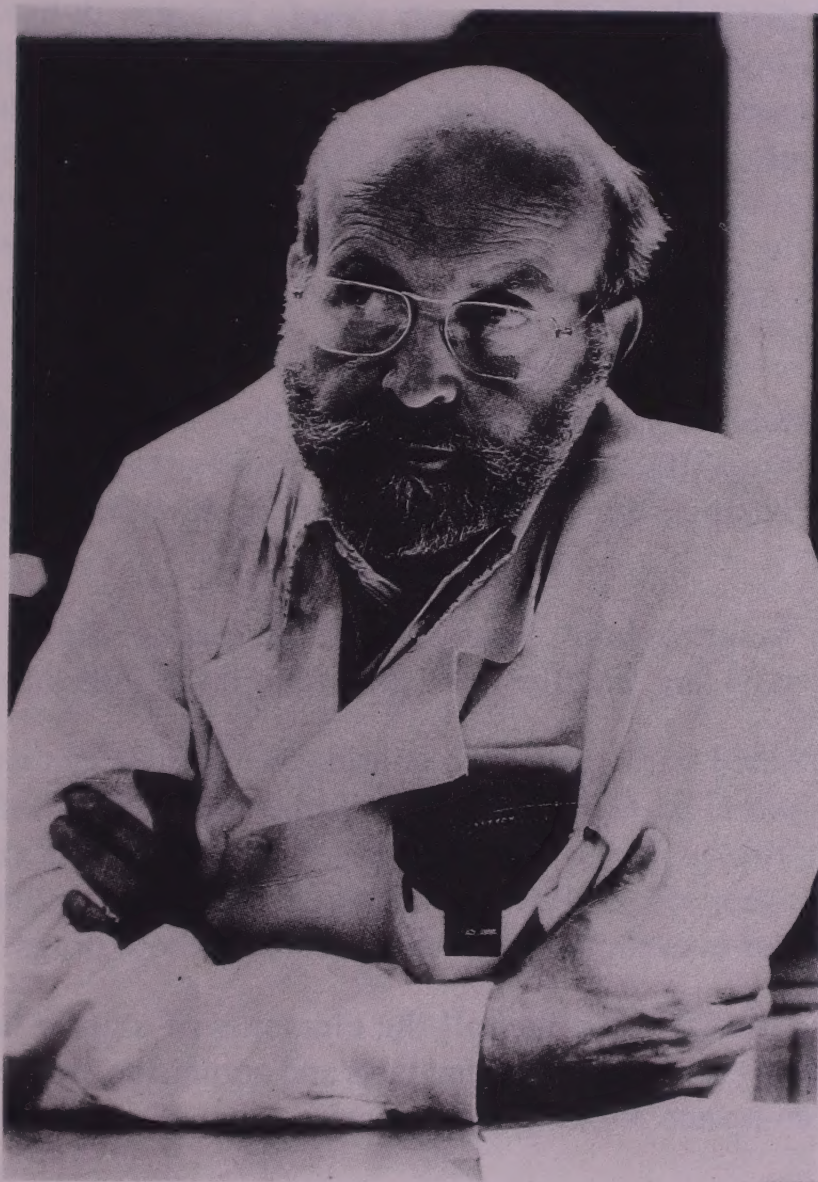
Health Action International shares its great concern with VHAI and urges the Government and the people of India to initiate activities to remove from the market all dangerous drugs.

Kind regards,

Sd/-
Dr. K. Balasubramaniam
International Coordinator/
Health Action International

Date: 26.4.1996

We Dedicate This Effort
to the memory of



Late Dr. Olle Hansson

One of the greatest health campaigners of our time, who believed in the patient's right to information, and firm adherence to medical ethics, who passed away on May 24, 1985.

Late Dr. Olle Hansson

Dr. Olle Hansson was a Swedish paediatric neurologist based in Gottenberg. His name is closely linked with his fight against Clioquinols (Mexaform-like drugs). Not merely did he provide scientific proof about absorption of the drug from the gut when ingested, (even when this was being systematically denied) but he was the first to report blindness associated with the drug. Dr. Olle Hansson wrote in scientific medical journals and in the lay press persistently for several years, warning the medical community and consumers about drug related hazards.

He stood as an expert witness in Tokyo District Court on behalf of the SMON* victims and their relatives - to support their fight for compensation against the giant multinational, Ciba - Geigy.

He fought a long, lonely battle against needless, drug induced suffering, and for "the patient's right to information".

Affected with cancer, he continued his fight against the Swiss giant Ciba-Geigy to ensure withdrawal of Mexaform, Enterovioform and Butazones. (Oxyphenbutazone, Phenylbutazone) - publishing information related to deaths and disability of over thousands after consuming these drugs.

Dr. Olle Hansson had all the elements of a great health campaigner - scientifically sound facts and arguments, persistence and perseverance, honesty and integrity coupled with humility.

His greatest attribute was his ability to inspire others with his incredible courage. He was the leading light in the consumer and health movement as he fought for truly rational and socially just use of drugs with humility which is a feature of truly great men.

*Subacute Myelo Optic Neuropathy

Remember Gandhi

For those manufacturing medicines and those making policies related to medicines, health and development - where decisions have to be made between profits and people. Remember- Gandhiji's words:

"Recall the face of the poorest and the most helpless man whom you may have seen and ask yourself if the step you contemplate is going to be of any use to him."

Mr. Justice B. Lentin (Retd.)

Examiner Press Building

2nd Floor

35, Dalal Street

Bombay -400 023

Tel. 2672780

March 6, 1996

Voluntary Health Association of India is and has been doing commendable work in bringing drugs awareness to the common man, and the live hazards of indiscriminate use of drugs. To this end, present updating of "Banned Bannable Drug List" is a salutary step and in the right direction.

While self-medication is harmful and even dangerous, even more deplorable is the apparent nonchalance of certain medical practitioners in indiscriminately prescribing drugs, and whose prescriptions read like horoscopes.

We have, in this country, far too many drugs and several of them with combinations which are next to worthless. If the present updating can bring awareness not only to the common man but also evoke a positive response from the medical profession, it shall have served its purpose.

Bakhtavar Lentin

Voluntary Health Association of India,
Tong Swasthya Bhawan,
40, Institutional Area,
South of IIT,
New Delhi - 110 016

(Like many areas of development policy, India took a lead in bringing out with an extra-ordinarily progressive report on Drug Policy, popularly known as Hathi Commission Report. In the ensuing years, many Governments and countries in south like Bangladesh have taken inspiration from this report to set up alternative Drug Policies in their own countries. But the policy in India have remained more or less static. Over the last few years with the new economic policy, perhaps this situation has deteriorated further. This, inspite of brave effort by the drug activists of India.

The book, "Banned and Bannable Drugs" has been a major weapon in the hands of drug activists of India. The revised version is being published to further add to the motivated struggle of numerous groups against this anti-people, anti-health drug policy. We hope the document will receive the attention that it deserves from planners, policy makers, medical professionals, voluntary organizations and the Commissions. We believe that committed work of this nature will some day bring about a sea change in the drug policy of India.)

Alok Mukhopadhyay
Executive Director, VHAI

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Help from Information Service and Communication Division of VHA I to the Division of People's Education for Health Action which has been mainly involved in production of the book is deeply appreciated.

Patient and excellent secretarial and general help was provided by Ms. Alphonse, Ms. Gloria David, Ms. Jessy George, Mr. D. Srinivasa Rao, Ms. Banasri Bhakta, Mr. Prabhakar Rao and Mr. Suresh Chauhan in the production of this book - a process which started way back in 1984. Support from colleagues Dr. P.V. Unnikrishnan and Mr. Sanjoy Sen Gupta is deeply appreciated.

The fourth revision of this book has been undertaken by Dr. Wishvas Rane and Dr. Mira Shiva.

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I

HOW TO USE THIS BOOK

This book is divided into two main sections - drugs that are banned by the Indian Government and those which are still allowed but which should be banned or severely restricted, because of their dangers.

- To learn why, and what alternatives are available, turn to the correct page. There you will find details of the dangers, various alternative names for the drug, what it is used for, a list of countries where the drug is already banned or restricted, an example of the contents of one of the brands on the market, and a suggestion for a safer or more rational alternative. Common brands have been printed in capitals for easy reference.

You will also find the names of brands listed as available in the commercial prescribing guides (MIMS, CIMS & DRUG TODAY) and in the Indian Pharmaceutical Guides' latest editions. MIMS and CIMS are used by doctors throughout the country as a source of drug information (in the absence of an unbiased source). Together, CIMS and MIMS influence the prescribing practices of several thousands of medical practitioners.

A large number of drugs not included in CIMS, MIMS and pharmaceuticals index are available in the market. It is hoped that a detailed list inclusive of those drugs will be made available to the public by the drug

licensing authorities, as they alone have information pertaining to these brands and manufacturers. It should also be noted that several drugs NOT included in the lists are available in the market. Hence the list of drugs being given here is just a minimal list.

In some cases the formulation is changed, so that recently manufactured products do not contain the hazardous drug which was there earlier. It is wise to check the label in case you are sold old (hazardous) stock. Some reformulated brands may have been included in the list, since there is no systematic way of knowing about reformulation. For the same reason, some withdrawn brands may have been retained in the list.

For further information, a list of available material on hazardous, irrational and useless drugs, rational drug use, the banning of drugs, drug policy etc. is provided at the end of the book, together with the source. Most of the material (except books and periodicals) is available from the Voluntary Health Association of India.

A few ideas for further action have been included on page 20 aimed at rational drug use for rational health care, to encourage greater awareness, and to stimulate action which will bring us nearer to a people-oriented and rational drug policy.

II

INTRODUCTION

Some of the information in this book should have been brought out by the Health Ministry after the 1982 Kerala High Court Judgement, which demanded that the list of banned drugs be made public. It could have come out even with the various Gazette Notifications of the Drug Controller of India banning 56 categories of harmful and irrational drugs. We have waited very long and if from need-based cyclostyled lists, a printed book has had to be produced, it has been done for some very specific and important reasons. This book has been done as:

- A response to increasing requests and demands from consumer and health groups and individuals for a list of drugs they should not prescribe or consume.
- An effort to focus the attention of the health personnel and consumer beyond brand names to the small print i.e. the content and generic names, the formulation for the reformulation.
- An effort to raise public awareness about the National Drug Policy in which the question of withdrawal of hazardous and irrational drugs, drug control, drug legislation, adverse drug reaction, unbiased drug information availability have been totally overlooked.
- An effort to ensure that conscientious health personnel and the public insist on representing their views, to safeguard their own health and health of their families.

- An attempt to highlight the need for international codes (besides national controls and legislations) where international agencies working for health, like WHO should take responsibility to ensure ethical marketing practices of powerful multinationals (the turnover of many multinationals is often far beyond the entire financial budgets of some developing countries). WHO's Ethical Criteria for marketing of drugs continues to be flouted.

The book is not merely a list of hazardous drugs. It is a tool for demanding action and demanding change. It is clear that no longer can people leave the safeguarding of their health entirely to the policy makers, the drug industry and medical professionals. From this book, consumers can check the contents of a medicine and ensure that they are not unnecessarily taking a hazardous drug. It is an effort to ensure that unbiased drug information is made available to health personnel for responsible prescription writing. Health personnel can demand an annually updated comprehensive National Drug Formulary with therapeutic guidelines so that availability of such information is ensured.

- India has one of the best developed pharmaceutical industries of the developing countries, and in spite of over 80,000 formulations in the market, there exist shortages and non availability of essential and life saving drugs in peripheral areas.
- Continuous flooding in the market of costly,

hazardous, and irrational drugs.

- About 20 per cent i.e. one in five of drugs tested are substandard and spurious.
- Lack of effective drug control and drug legislation.
- Non-availability of unbiased drug information.
- Increasing privatization of drug dispensing and drug prescribing with a move towards fee for service from Govt. health infrastructure.
- Increasing drug prices....

[All these are totally unacceptable in a democracy. We are a country with the world's third largest medical manpower. We are signatory to the Alma Ata Charter of 1978 and we have issued a very progressive sounding National Health Policy statement in 1983. We are acknowledged as a Third World leader. Yet it is here where half the people live below the poverty line, that half of the world's T.B. patients, one third of the world's leprosy patients struggle to survive. Here 1.5 million children still die of preventable and easily treatable diarrhoeas.

The impact of Structural Adjustment programmes on social sectors like health have been significant.

Resurgence of epidemics of Plague, Malaria, Hepatitis, Cholera, in the recent years is a matter of concern and so also is the unparalleled spiralling of drug prices and medical care costs.

Medical expenditure by those who are most vulnerable to ill health and who have little

purchasing power has resulted in medical loans as one of the major cause of rural indebtedness.

Emergence of drug resistance with communicable diseases, resistance to pesticides and spread of vector borne diseases has resulted in serious concerns for the future.

Pressure to change the model Indian Patent Act of 1971 in keeping in with WTO (World Trade Organisation) will have its own implications in terms of increased costs and decreased access and affordability.

Drug Policy was formulated in 1986 and then in 1994 in keeping with the new Industrial Policy and a shift towards decontrol, liberalization, deregulation, health, consumer and women's group maintain that there should be no liberalization without and Rationalization. What we are seeing is the former without the latter.

The Banned Bannable Drug List is a reminder about the latter and is a tool for health awareness and health action.

Medicines cannot be treated as a mere profitable, yet unessential, commodity like cosmetics. They have a role in health care, limited though it may be. Commercialization and pharmaceuticalization of health care has to be resisted. Socially conscious health personnel and public can help create a sensible market demand. Refusing to prescribe and consume hazardous and irrational drugs is the first step in this effort.

With the increasing commercialization of health care, its increasing cost and dependency on costly technologies, it is extremely critical to differentiate between essential rational drugs/

medical technologies vs. profit-oriented, non-essential, irrational and hazardous drugs/medical technologies.

Led by Dr. Olle Hansson, over 3,000 doctors in Sweden, Denmark, Finland and Norway boycotted Ciba-Geigy products for its continued sales of Mexaform and Enterovioform in the Third World (See the Clioquinol Section for over a hundred brands being sold in India and the names of the manufacturers). The boycott which resulted in a fall in the drug sales of Ciba Geigy products linked with economic losses and therefore withdrawal of the product.

Several health and consumer groups who feel strongly about these issues have been actively involved in drug and health education and in promoting health action to meet contemporary health challenges. The All India Drug Action Network (AIDAN) in India, Action for Rational Drugs in Asia (ARDA), and Health Action International (HAI) are examples of such coordinated health action. Responding to their social responsibility, physicians who have protested against use of nuclear energy for destruction were the recipients of the Nobel Prize which merely indicates that today there is a crying need for socially responsible action of professionals and consumers alike.

There are very few areas where people can so actively influence and bring about change as in the drugs issue. Once people refuse to prescribe and take hazardous and irrational medicines, change is entirely in their own hands.

Efforts towards humanized, health care, humanized living and humanized ecological sustainable development are interconnected. Refusal to accept pills and policies destructive

to mankind is part of the same effort, and a part of the same process.

This peaceful resistance against hazardous and irrational drugs and exploitative health care is essential in the self-interest of individuals and in the interest of society. Consumer groups call it "Boycott"; Gandhi, called it "Satyagraha". A call for "Rational Drug Use is a reflection of that spirit and is a call for action.

The drug policies formulated so far have failed to safeguard public interest. Hathi Committee was appointed in 1974 to undertake a thorough analysis of the Indian drug industry. The Hathi Committee made some important observations and recommendations such as:

- IT ATTEMPTED FOR THE FIRST TIME A FORMULATION OF AN ESSENTIAL DRUG LIST. (IN LAST 20 YEARS AND TILL NOW NO ESSENTIAL DRUG LIST HAS BEEN EVOLVED OR ADOPTED BY THE GOVERNMENT).
- It recommended a gradual shift to GENERIC names from brand names. The shift to generic names was blocked by Hoechst, Cyanamid and Pfizer by obtaining stay orders from Delhi High Court in 1981 and the case continues to languish in Supreme Court and a final judgement was awaited as of May 1995.
- The price control basket has systematically shrunk with each DPCO.
From 343 drugs in 1979
to 142 drugs in 1986
to 76 drugs in 1995
- It recommended a package of price control measures to make life saving and essential drugs affordable. (DPCO 1979, started with a categories of drugs with price

controls ranging from 40 percent to 55, 75 and 100 percent and the open category of non-essential and simple remedies with unlimited profits. Drug Price Control Order (DPCO) 1987 raised the profit margin of category I drug to 75 percent and Category II to 100%, decontrolling the rest.. DPCO 1995 has abolished the different categories and the category I & II are brought under a single common list with uniform MAPE of 100 percent and the rest of the drugs being price decontrolled. The price control basket has systematically shrunk with each DPCO. From 343 drugs in 1979 to 142 drugs in 1986 and 76 drugs in 1995.

NONE OF THESE MEASURES HAVE MADE ESSENTIAL LIFE SAVING DRUGS ADEQUATELY AVAILABLE AT AFFORDABLE PRICES, BUT THE NON-ESSENTIALS HAVE PROLIFERATED, AS IS OBVIOUS FROM TABLE 1.

The brand names are taken from MIMS (June 1995) CIMS (Mar-Aug 95). Drug Today (July-Sept.95) and Indian Pharmaceutical Guide (1994). There is a possibility that a few of these brand name products may not be available, but because the brand names are included in the reference guides, the same are mentioned. There is also a possibility that since the enforcement of government ban order, a few of the manufacturers may have reformulated but kept the same brand names. We shall be obliged if the readers inform us of such changes or discrepancies to enable us to effect the corrections in the subsequent editions. In some cases the brand names are purposefully given in a misleading way. For example Phensedyl contains promethazine (antihistamine) with codeine and ephedrine. Combination of ephedrine with antihistaminic is banned as a

cough mixture. So they do not call this as a cough remedy. Instead they have another preparation with a brand name 'Phensedyl expectorant' which contains only antihistamine with guaicol and menthol.

Of the 80 top selling products, 23 (nearly 30 percent) are either irrational, or hazardous or both. The combined sale of these 23 drugs was Rs. 286.63 crores, i.e. almost 10 per cent of the total sales in 1992. This clearly shows that the earlier two DPCO's (1979 and 1987) have helped in the growth of irrational drug combinations. The new DPCO 1995 has further reduced the number of products under price control and it will further increase the irrational and non-essential drugs and drug combinations. In the circumstances a book like Banned and Bannable Drug List gains more importance. (See list and growth of some irrational drugs in the next page).

With rapid development in Science and Technology there has been an explosion in the number of drugs which are available in the market. US FDA has reported that of the 348 new drugs from US drug companies between 1981 and 1988, 3 percent made a modest potential contribution, and 84 percent made little or no potential contribution. A French study of 508 new Chemical entities marketed in the world between 1975 and 1984 found 70 percent offered no therapeutic improvement over existing products. The situation in India is no different and will probably worsen over a few more years of liberalisation and decontrol.

There are an estimated 60 to 80 thousand brands of various drugs available in the Indian market. In such a situation and particularly where majority of the drugs are fixed dose combinations, the task of an already overstretched Drug Control Authority becomes

almost impossible to cope with.

The 14 deaths of innocent ophthalmic patients due to use of industrial glycerol in J.J. hospital, Bombay (referred to in detail in Lentin Commission Report) and 7 deaths to life saving I.V. Fluid in Delhi show the state of quality control in India. How can the quality of hazardous or irrational drugs be assured? Such drugs must be withdrawn, so as not to overload the already inadequate drug control machinery and ensure low cost and good quality of essential life saving drugs.

The question is no longer just of economic wastage. In a country with around 40 percent of the population below or around the poverty line, it is a matter of serious concern and exploitation in the name of medicine. The issue of medicines is a rapidly emerging public health problem. In the absence of monitoring of adverse drug reactions i.e. the side effects of medicines, majority of the cases of iatrogenesis i.e. "doctor induced problems" the reaction of additional problems or complications resulting from treatment by a physician or surgeon, continue to be missed. It is only tragedies such

as Thalidomide Tragedy, DES and Halcion Tragedy, the glycerol deaths and deaths due to contaminated I.V. fluids that focus public attention on the problems related to unsafe medicine.

A Public Interest Litigation has been filed in the Supreme Court in 1993 to screen and weed out irrational and hazardous drugs by All India Drug Action Network, Drug Action Forum-Karnataka, NCCDP and other Voluntary Health Organisations eg. Locost, CDMU etc.

Several therapeutic categories of drugs have since been banned and others have been theoretically restricted.

Revision of the "Banned and Bannable Drugs" is VHAI's contribution to the ongoing effort towards Rational Drug use and Rational Drug Policy.

Dr. MIRA SHIVA, M.D.

Head of Division

Public Policy

Voluntary Health Association of India

Note: "Measures for Rationalisation" The New Drug-Policy announced by the Ministry of Chemicals and Fertilizers has been a great let down to the public.

Table 1
Sales of some Irrational Drugs in 1992 (in Rs.Crores)

<i>Rank</i>	<i>Drug</i>	<i>Description</i>	<i>Sale</i>	<i>Growth percent</i>
6	Becosule	Irrational Vitamin Combination	23.92	0.50
10	Dexorange Plus	Tonic	20.11	17.0
16	Liv 52	Useless Liver Drug	17.80	15.80
17	Neurobion	Irrational Vitamin Combination	15.88	31.00
20	Electral	Irrational ORS	16.83	24.4
24	Revital	Oral Ginseng Tonic	15.05	19.00
26	Corex	Irrational Cough Mixture	13.83	12.20
28	Benadryl	Irrational Cough Mixture	13.56	2.10
30	Ampoxin	Irrational Antibiotic Combination	13.30	0.30
32	Baralgan	Hazardous Antispasmodic	13.17	10.20
35	Cobadex Forte	Irrational Vitamin Combination	12.88	39.30
36	Combiflam	Irrational Analgesic Combination	12.78	23.40
38	Polybion	Irrational Vitamin Combination	12.48	10.40
41	Phensedyl	Irrational Cough Mixture	15.96	1.20
44	Gelusil MPS	Irrational Antacid Combination	10.72	21.00
48	Novalgin	Hazardous Analgesic	10.53	15.30
56	Complan	Food Product	9.23	6.00
63	Vicks Vaporub	Useless Cold Remedy	8.71	27.60
66	Ostocalcium	Irrational Calcium Combination	8.67	6.30
71	Haem-Up	Irrational Tonic	8.50	18.30
72	Enteroquinol	Hazardous Antidiarrhoeal	8.43	16.50
77	Macalvit	Calcium Syrup	8.09	6.30

Source: ORG 1993

Products showing Price Rise more than 50 per cent

<i>Product</i>	<i>Company</i>	<i>Packing</i>	<i>Rate on</i>		<i>Per Cent Rise</i>
			<i>December 1993</i>	<i>September 1995</i>	
Gesicaine (1 per cent)	S G Pharma	30 ml	3.48	11.17	220.98
Fristina	MAC	110 ml	6.10	19.52	220.00
Kenalog S	Sarabhai	2.5 gm	2.53	8.03	217.39
Otoflour	Bell Pharma	10 T	4.00	12.00	200.00
Glucagon	Torrent	vial	114.98	330.00	187.01
Stadmed Entrozyme	Stadmed	45 ml	7.51	21.30	183.62
Mycoderm	FDC	100 gm	15.25	22.40	181.67
Fungizone IV	Sarabhai	50 mg	55.51	150.00	170.22
Midarine	Burroughs Wellcome	2 ml	3.42	6.93	181.58
Bell Homatropine (2 per cent)	Bell Pharma	10 ml	5.62*	14.90	165.12
Capsovit forte	Pharmed	30 C	9.20	24.00	160.87
Mac Soralen	Mac	15 ml	6.80	17.66	159.71
Walavin FP	Wallace	10 T	8.80	22.77	158.75
Bell Diono Resolvent	Bell	3 gm	5.90	15.00	154.24
Bell Resolvent	Bell	3 gm	5.05	12.80	153.47
Hematrine	Sandoz	40 C	16.16	40.00	147.52
Daktacort	Ethnor	5 mg	7.93	19.60	147.16
Epsolin	Cadila	2 ml	1.01	2.47	144.55
Depsonil PM	S G Pharma	10 C	6.58	16.05	143.92
Bell Homa (1 per cent)		10ml	4.20	10.15	141.67
Septopal	Merck		1534.41	3672.46	139.37
Algipan	Wyeth	20 gm	7.43	17.70	138.22
Broacil dry syp	IDPL	40 ml	9.61	22.61	135.28
Copamide	Dey's	10 T	1.73	4.00	131.21
Capto Miotic (2 per cent)	Bell	10 ml	13.80	31.80	130.43
Marax	Unimed	20 T	12.83	28.81	124.55
Nutrisan	Sandoz	30 C	13.55	30.00	121.40
Bellpino Artrina	Bell	5 ml	4.65	10.00	115.00
Alludrox Gel	Wyeth	350 ml	13.49	28.93	114.46
Myambutol	Cyanamide 400 mg	10 T	5.92	12.64	113.51
Gesicaine (1 per cent)	S G Pharma	30 ml	4.16	8.83	113.22
Biomiotic	Bell	10 ml	18.80	40.00	112.77
Tivision	Bell	10 ml	4.70	10.00	112.77
Corex	Pfizer	60 ml	9.39	19.55	108.20
Testanon-25	Infar	1 ml	5.00	10.40	108.00
Lanoxin	Burroughs Wellcome	10 T	1.95	4.00	105.13
Dilantin	Parke Davis	100 T	21.65	44.41	105.13

Source: Dr. W.V. Rane, Economic and Political Weekly, November 25, 1995

Productwise Price Rise

<i>Category System</i>	<i>No. of Products Showing Per cent Price Rise of</i>					
	<i>0-10</i>	<i>10-20</i>	<i>20-30</i>	<i>30-40</i>	<i>40-50</i>	<i>Over 50</i>
Alimentary	28	10	4	1	2	3
Cardiovascular	27	23	12	10	3	9
Central nervous	49	30	11	13	4	20
Musculoskeletal	17	5	7	4	6	3
Hormones	31	13	13	4	2	9
Genito-urinary	13	9	6	1	2	3
Infections	110	22	22	12	5	17
Nutrition	65	29	19	12	7	8
Respiratory	20	12	9	5	—	9
Ear-Nose-Throat	5	2	2	2	6	
Eye	10	6	4	3	5	17
Allergic	4	2	4	3	4	2
Skin	27	12	15	11	2	11
Others	1	14	10	2	2	11
Total Products (3,607)	403	192	138	83	46	137
Per cent	11.17	5.32	3.83	2.30	1.28	3.80

Source: Dr. W.V. Rane, Sharp Rise after Decontrol, Economic and Political Weekly, November 25, 1995
Pg. 2977-2980

III

CONSUMER ACTION

WHAT YOU CAN DO

Know your medicines

1. Stop using banned and hazardous drugs.
2. Stop using useless and irrational drugs.
3. Tell your family, friends, neighbours and community about banned, bannable, hazardous and useless drugs. Inform them of safer and better alternatives. Always ask for a cash memo and keep it safely, which is necessary for any possible consumer action.
4. Inform local doctors, chemists and health workers.
5. Avoid combination drugs. Buy single ingredient drugs as far as possible.
6. Avoid expensive brand-named drugs, buy the generic equivalents, but of reliable companies.
7. Refuse to take a drug if it's expiry date is over, or if it is discoloured and if there are suspended particles in it. **LOOK AT THE EXPIRY DATE** before purchasing drugs.
8. Report all drug shortages to your State Health Secretary, Director General Health Services and The Drug Controller of India, VHA1 and AIDAN. (Addresses are given at the back of the book).
9. Encourage the use of traditional home remedies, instead of expensive and unnecessary drugs for trivial problems.
10. Encourage and demand preventive health measures like potable drinking water supply, sanitation, enough nutritious food, appropriate immunization, essential health services healthy environment and safe working conditions so that diseases do not occur in the first place.
11. Whenever you are prescribed a drug, ask your doctor politely what side-effects may occur, how long you should continue taking the drug, what are the expected benefits, and whether you should avoid certain food or drink while taking the drug. Encourage other people to obtain this important information from their

doctors, especially in the case of pregnancy, liver or kidney damage, or known drug sensitivity. Know your rights as a patient.

12. Support health, drug action, consumer, social action and other groups which are striving for rational drug use and justice in health care.
13. Monitor the inclusion or absence of package inserts (printed information with drug packs). Inform Drug Controllers and VHAI of cases where the package insert is absent for life saving drugs.
14. If given a very long prescription, find out which are the most essential drugs for your health problem and which can be avoided. e.g. costly tonics that could be substituted by food. This can be ascertained from your doctor. (Studies have shown that many patients due to resource crunch can buy the drugs only for one day and that they can buy only the first one or two drugs listed on long prescriptions).
15. Ensure that anyone prescribed antibiotics or put on long term treatment, as for TB or leprosy, takes his/her medicine regularly and for proper length of time to avoid emergence of drug resistance.
16. For basic information on use of drugs refer to "Where There Is No Doctor" by David Werner (available with VHAI). The green pages deal specifically with drugs and their dosages, their indications, precautions, etc.
17. Form a Local Health Committee and supervise availability and utilisation of the drugs in government health institutions eg.

primary health centres and dispensaries.

18. Report side effects if any, to your doctor.

For Health Personnel

19. Educate your community about hazardous and useless drugs, and alternative remedies, using posters, puppet shows, street theatre, slide shows, public meetings, articles and letters in the local newspapers, publications in local languages, etc.
20. Form an action committee of concerned groups and individuals to create awareness of the situation, and bring about change. Link up with VHAI, All India Drug Action Network and its members.
21. Encourage your local health workers to recommend drugs only when necessary, to suggest appropriate home remedies for trivial complaints.
22. Encourage your local doctors to prescribe only essential and appropriate single ingredient drugs (despite pressure to do otherwise from both the patients and the drug salesman).
23. To help facilitate monitoring of continued sales of banned drugs, you can buy banned drugs, obtain a cash memo and send copies to your State Drug Controller, the Drug Controller of India and VHAI.
24. Introduce your local doctors and health workers to sources of unbiased, up-to-date drug information (see Annexure 2) so they are not solely reliant on drug companies' sales literature and commercial prescribing guides.

25. Report to your State Drug Controller. The Drug Controller of India and VHA any incentive schemes, or free gifts offered to doctors in return for buying or prescribing certain drugs.
26. Conduct a drug utilization study in your area. Find out how drugs are being misused or overused, how much people are spending on useless drugs, whether they are using hazardous drugs, whether health workers have up-to-date drug information from unbiased sources, how many drugs are sold over-the-counter or by prescription only. Publicise the results and work to improve the situation.
27. Study the commercial prescribing guides (eg. MIMS and CIMS, Drug Today, see Annexure 2), sales literature of the drug companies and the labels/package insert of drugs. Compare this information with standard text books. Look particularly at the contra-indications (conditions when the patient should not take the drug) and warnings of side effects. Inform the publishers of the commercial guides, drug companies concerned, Drug Controllers, AIDAN and VHA of any significant differences you find between the commercial information and that contained in the text books.
28. Study the contents of popular brands of over-the-counter painkillers etc. Discover whether they contain any hazardous drugs and whether the active ingredients are included in sufficient amounts to be useful. Compare the price. Publicise your results.
29. Compare the increase in present year's from previous year's drug prices and availability of essential and life saving

drugs, especially drugs for National Health Programmes.

30. Support any initiatives to preserve, document or improve traditional local health care system which can increase self-reliance.
31. Educate your community about the irrationality and high cost of tonics. Show how much good food one can buy for the price of a bottle of tonic.
32. Organise a local Oral Rehydration Campaign, so that every household knows the best treatment for diarrhoea and how to prepare it from household ingredients. Warn people of the dangers and uselessness of most anti-diarrhoeal drugs, and the dangers of not giving oral rehydration, especially to young children in early diarrhoea (see Annexure 2 for sources of further information on diarrhoea care).

Find out about the Adverse Drug Reaction of the drugs that you prescribe specially drugs used in PREGNANCY for Teratogenic effects of drugs.

33. Report Adverse Drug Reactions encountered by you in your practice to ADR monitoring centres.

Note: There is a WHO Ethical Criteria for marketing of drugs and an International Pharmaceutical manufacturers Association Code of conduct in drug marketing. Inform them and us of violations.

UNETHICAL MARKETING PRACTICES AND DOUBLE STANDARDS

The market for non essential irrational and even hazardous drugs will continue to grow till there are policies that protect the consumers, or

consumers that protect themselves. One of the most important tool for rational consumption of drugs is access to unbiased drug information.

Not merely are Brands promoted with suppressions of the negative facts but half truths are told to misguide.

In the past, reference of Lancet has been used in the promotional package by Glaxo promote Osteocalcium B-12 when there was no

such endorsement from Lancet.

Boehringer Knoll used UNICEF Logo to promote its Chloramphenicol Streptomycin combination as antidiarrhoeal.

Several products are not allowed to be sold in the parent country Organon (Infar's) High dose Estrogen progesterone combination MENSTROGEN was a perfect example.

Restricted use of Drugs is only possible if

Some of the others are:

Name of the Drug.	Company	Country of origin	Indications for which the drugs are promoted
Avil Expectorant	Hoechst	F.R.G.	Cough Expectorant
Soventol Expectorant	Boehringer Knoll	F.R.G.	-do-
Piriton Expectorant	Glaxo	U.K.	-do-
Periactin	Merind (MSD)	U.S.A.	Appetite Stimulant
Ostocalcium B12	Glaxo	U.K.	Growth Tonic
Amebiotic	Pfizer	U.S.A.	Anti Diarrhoeal
Baralgan	Hoechst	F.R.G.	Anti Spasmodic
Suganril	S.G. Chemical (CIBA Giegy)	SWISS	Anti inflammatory Containing phenyl or oxyphenbutazone

there is an effective system of provision of unbiased drug information.

Changes of indications on paper, to escape the drug bans even when they do come too late and too ineffectual - takes care of the legal aspects without really affecting the sales and the market negatively.

Further privatization of health care

services is bound to increase the use of non essential irrational and even hazardous drugs.

Further non formulation and non implementation of an Essential Drug Policy and an Essential drug list results in more and more usage of irrational and non essential drugs by health institutions, health personnel and consumers.

Ref.: Rational Drug Policy Problems, Perspective and Recommendations. VHAI-AIDAN 1986.

BANNING OF DRUGS

COMPARISON OF PREVIOUS RECOMMENDATIONS WITH THE GAZETTE NOTIFICATION OF JULY 1983 and GAZETTE NOTIFICATION SINCE THEN TILL 1995

You can compare the drugs which were recommended for banning by experts, with the drugs which were actually banned, by following the lists horizontally from left (the first recommendations) to right (the ban order). Many of the recommendations were not followed. The number in brackets indicates order in the original document.

Recommended by sub-committee of Drug Consultative Committee: 1980	Drug Technical Advisory Board Report, 25 May 1982	Gazette Notification of Drug Controller of India July 23, 1983. No.X 1014/1/83.
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To be weeded out immediately.

1. Fixed dose combination of steroids.	(15) Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for treatment of asthma.	(14) ¹ Fixed dose combinations of steroids for internal use except combinations of steroids with other drugs for treatment of asthma
2. Fixed dose combinations of amidopyrine	(1) Fixed dose combinations of amidopyrine.	(1) Amidopyrine
3. Fixed dose combinations of chloramphenicol	(16) Fixed dose combinations of chloramphenicol except preparation of chloramphenicol and streptomycin.	(15) ² Fixed dose combinations of chloramphenicol for internal use except combinations of chloramphenicol and streptomycin.
4. Fixed dose combinations of ergot	(17) Fixed dose combinations of ergot except combinations of its alkaloid ergotamine with caffeine.	(16) Fixed dose combinations of ergot.

- | | |
|---|---|
| 1 | Fixed dose combination of corticosteroids with any others drugs for internal use was banned in 1988 |
| 2 | Fixed dose combination of chloramphenicol with any other drugs for internal use was banned in 1988 |

Recommended by sub-committee of Drug Consultative Committee: 1980	Drug Technical Advisory Board Report, 25 May 1982	Gazette Notification of Drug Controller of India July 23, 1983. No.X 1014/1/83.
5. Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.	(2) Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.	(2) Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.
6. Fixed dose combinations of atropine in analgesics and anti-pyretics.	(3) Fixed dose combinations of atropine in analgesics and anti-pyretics.	(3) Fixed dose combinations of atropine in analgesics and anti-pyretics.
7. Fixed dose combinations of analgin.	(Excluded)	(Excluded)
8. Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins.	(5) Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins.	(5) Fixed dose combinations of yohimbine and strychnine with testosterone and vitamins.
9. Fixed dose combinations of iron with strychnine, arsenic and yohimbine.	(6) Fixed dose combinations of iron with strychnine, arsenic and yohimbine.	(6) Fixed dose combinations of iron with strychnine, arsenic and yohimbine.
10. Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.	(7) Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.	(7) Fixed dose combinations of sodium bromide/chloral hydrate with other drugs.
11. Fixed dose combinations of tetracycline, analgin with vitamin C.	(13) Fixed dose combinations of tetracycline with vitamin C.	(12) Fixed dose combinations of tetracycline with vitamin C.
12. Fixed dose combinations of ayurvedic drugs with modern drugs.	(8) Fixed dose combinations of Ayurvedic and Unani drugs with modern drugs.	(Excluded)
13. Fixed dose combinations of phenacetin.	(9) Fixed dose combinations of phenacetin.	(8) Phenacetin.
14. Fixed dose combinations of chloramphenicol with streptomycin.	(Excluded)	(Excluded)
15. Fixed dose combinations of penicillin with streptomycin.	(Excluded)	(Excluded)
16. Fixed dose combinations of more than one anti-histaminic.	(Excluded)	(Excluded)

To be weeded out over specific time

1. Fixed dose combinations of anti-histaminics in anti-diarrhoeals.	(10) Fixed dose combinations of anti-histaminics with anti-diarrhoeals.	Fixed dose combinations of anti-histaminics with anti-diarrhoeals.(9)
2. Fixed dose combinations of penicillin with sulphonamides.	(11) Fixed dose combinations of penicillin with sulphonamides.	(10) Fixed dose combinations of penicillin with sulphonamides.
3. Fixed dose combinations of anti-histaminics with tranquilizers.	(Excluded)	(Excluded)
4. Fixed dose combinations of tranquilizers, anti-histaminics and analgesics.	(Excluded)	(Excluded)
5. Fixed dose combinations of vitamins with analgesics.	(12) Fixed dose combinations of vitamins with analgesics.	(11) Fixed dose combinations of vitamins with analgesics.

Recommended by sub-committee of Drug Consultative Committee:1980	Drug Technical Advisory Board Report, 25 May 1982	Gazette Notification of Drug Controller of India July 23, 1983. No.X 1014/1/83.
6. Fixed dose combinations of paracetamol with anti-histminics and tranquilizers	(Excluded)	(Excluded)
7. Fixed dose combinations of prophylactic vitamins in anti TB drugs except IN with vitamin B6.	(18) Fixed dose combinations of prophylactic vitamins with anti TB drugs except combination of INII with vitamin B6.	(17) Fixed dose combinations of vitamins with anti TB drugs except combination of Isoniazide with Pyridoxine Hydrochloride (Vitamin B6).
<i>Additions to DCC List</i>	(4) Fixed dose combinations of strychnine and caffeine in tonics.	(4) Fixed dose combinations of strychnine and caffeine in tonics.
	(14) Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery	(13) Fixed dose combinations of hydroxyquinoline group of drugs except preparations which are used for the treatment of diarrhoea and dysentery and for external use only.
<i>Additions to DTAB List</i>		(18) Penicillin skin/eye ointment
		(19) Tetracycline liquid oral preparations
		(20) Nialamide
		(21) Practolol
		(22) Methapyrilene, its salts.
Addition of Gazette Notification 1984		(23) Methaqualone (23)
		(24) Oxytetracycline liquid oral preparations
		(25) Demeclocycline liquid oral preparations
Addition to Gazette Notification 1985		(26) Combination of anabolic steroids with other drugs.
		(27) High dose estrogen and progestin combinations.

Note: For fixed dose combinations see page 30.

Addition to Gazette Notification 1988

*(14)¹ Fixed dose combination of corticosteroids with any other drug for internal use.

*(15)² Fixed dose combination of chloramphenicol with any other drug for internal use.

Additions to Gazette Notification 1990

Issued on : 26.12.90

Issued by : Balbir Singh Jt. Secretary

Gazette Notification of Drug Controller of India No.X 11014/3/88. DMS & PFA

28. Fixed dose combinations of Sedatives/hypnotics/anxiolytics with analgesic-antipyretics.

29. Fixed dose combination of Pyrazinamide with other anti-tubercular drugs except combination of Pyrazinamide with Rifampicin and INH as per recommended daily dose given below :-

Drugs	Minimum	Maximum
Rifampicin	450 mg	600 mg
INH	300 mg	400 mg
Pyrazinamide	1000 mg	1500 mg

30. Fixed dose combination of histamine H₂-receptor antagonists with antacids except for those combinations approved by the Drugs Controller, India.

31. The patent and proprietary medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.

32. All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or v/v whichever is appropriate.

Additions to Gazette Notification 1991

Issued on : 11.2.91

Issued by : Balbir Singh Jt. Secretary

Gazette Notification of Drug Controller of India No.X 11014/4/90. DMS & PFA

33. Fixed dose combination of Ethambutol with INH other than the following:-

INH	Ethambutol
200 mg	600 mg
300 mg	800 mg

1. In July 1993 Fixed dose Combinations of Steroids for internal use **except combinations of steroids with other drugs for treatment of asthma** were banned. See 14 page 29.
2. Similarly fixed dose combinations of chloramphenicol for internal use **Except combinations of chloramphenicol and streptomycin** were banned. See 15 page 29.

34. Fixed dose combination of anthelmintic with cathartic/purgative except for piperazine.

35. Fixed dose combination containing more than one antihistamine.

36. Fixed dose combination of Salbutamol or any other bronchodilator with centrally acting anti-tussive and/or antihistamine.

37. Fixed dose combination of laxatives and/or anti-spasmodic drugs in enzyme preparations.

38. Fixed dose combination of Metoclopramide with other drugs except for preparations containing metoclopramide and aspirin/paracetamol.

39. Fixed dose combination of centrally acting anti-tussive with antihistamine having high atropine like activity in expectorants.

40. Preparations claiming to combat cough associated with asthma containing centrally acting anti-tussive and/or an antihistamine.

41. Liquid oral tonic preparations containing glycerophosphates and/or other phosphates and/or central nervous system stimulant and such preparations containing alcohol more than 20 proof.

42. Fixed dose combination containing pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed.

Additions to Gazette Notification 1992

Issued on : 30.4.92

Issued by : B.S. Lamba Jt. Secretary

Gazette Notification of Drug Controller of India No.X 11014/3/91. DMS & PFA

43. Chloral Hydrate as drug

44. Tooth paste/Toothpowder containing Tobacco

45. Dovers Powder/Dovers Powder Tablets

Additions to Gazette Notification 1994	Issued on : 30.9.94 Issued by : Shailja Chandra Jt. Secretary	Gazette Notification of Drug Controller of India Sept. 30, 1994 No.X 11014/4/90. DMS and PFA
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46. Antidiarrhoeal formulations containing Kaolin or Pectin or Attapulgit or activated charcoal.

47. Antidiarrhoeal formulations containing Phthalyl Sulphathiazole or Sulphaguanidine or Succinyl Sulphathiazole.

48. Antidiarrhoeal formulations containing Naomycin or Streptomycin or Dihydrostreptomycin including their respective salts or esters.

49. Liquid Oral antidiarrhoeals or any other dosage form for paediatric use containing Diphenoxylate or Loperamide or Atropine or Belladonna including their extracts or their alkaloids.

50. Liquid oral antidiarrhoeals or any other dosage form for paediatric use containing halogenated hydroxyquinolines.

51. Fixed dose combination of antidiarrhoeals with electrolytes.

Additions to Gazette Notification 1995	Issued on : 7.2.95 Issued by : Shailja Chandra Jt. Secretary	Gazette Notification of Drug Controller of India Feb. 7, 1995 No.X 11014/8/94. DMS and PFA
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52. Patent and Proprietary Oral Rehydration Salts other than those conforming to the different parameters. (See the updated BBDL)

Additions to Gazette Notification 1995	Issued on : 15.9.95 Issued by : Indrajit Choudhuri Addl. Secretary	Gazette Notification of Drug Controller of India No.X 11014/2/95. DMS and PFA
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53. Fixed dose combination of Oxyphenbutazone or Phenylbutazone with any other drug.

54. Fixed dose combination of Analgin with any other anti-spasmodics.

55. Fixed dose combination of dextropropoxyphene with any other drug other than anti-spasmodics and/or non-steroidal anti-inflammatory drugs (NSAIDS).

56. Fixed dose combination of a drug, standards of which are prescribed in the Second Schedule to the said Act with an Ayurvedic, Siddha or Unani drug.

BANNED DRUGS

Countries which have never allowed these drugs, and therefore do not need to ban them, are NOT listed here., Other countries, which have a legal structure which discourages the introduction of hazardous or irrational drugs, or strong medical associations which ensure withdrawal of such drugs without their having to be banned are also NOT listed.

**1. AMIDOPYRINE/
(AMINOPHENAZONE/
AMINOPYRINE/
DIMETHYLAMINOANTIPYRINE/
DIMETHYLAMINO
PHENYLDIMETHYL
PYRAZOLONE/DIPYRINE)**

Brand

Manufacturer

Nil

Nil

REASON FOR BANNING : Dangerous. Can

cause fatal agranulocytosis^{1,1} and aplastic anaemia. Much safer and cheaper alternatives are available.

“The risk of agranulocytosis...is sufficiently great to render this drug unsuitable for use. Onset of agranulocytosis may be sudden and unpredictable”.^{1,2}

“Amidopyrine is considered toxic because:

- (a) causes high incidence of agranulocytosis.
- (b) In some individuals it may cause a sharp fall of total leucocyte count associated with chill, fever, headache and pain in muscles and joints following the administration of drug”.^{1,3}

USED : For pain, fever, inflammation.

**COUNTRIES WHERE BANNED,
WITHDRAWN OR RESTRICTED:**

Australia, Austria, Belgium, Chile, Denmark, Finland, France, Greece, Italy, Japan,

1.1. See glossary

1.2. Martindale: The Extra Pharmacopocia, 28th edition 1982

1.3. Drug Consultative Committee Recommendation, 1980

Kuwait, Korea, Mauritius, Nepal, Philippines, Rumania, Saudi Arabia, Singapore, Switzerland, Thailand, Turkey, Venezuela, West Germany, Yemen.

SAFER ALTERNATIVES: For fever: Paracetamol or aspirin; for pain and inflammation: aspirin.

2. FIXED DOSE COMBINATIONS OF VITAMINS WITH ANTI-INFLAMMATORY AGENTS AND TRANQUILLIZERS.

Drugs containing anti-inflammatory agents, tranquilizers and vitamins together though present in the market, are not listed in MIMS, CIMS or the Pharmaceutical Guide. Their presence in the market cannot be commented upon. Combinations of anti-inflammatory agents with vitamins, and tranquillizers with vitamins are listed under 'Gazette Ambiguities.

3. FIXED DOSE COMBINATIONS OF ATROPINE/BELLADONA/HOMATROPINE/SCOPOLAMINE IN ANALGESICS AND ANTI-PYRETICS.

REASON FOR BANNING: Dangerous. Atropine may block the sweating response which helps to lower temperature, thus making the anti-pyretic (fever-reducer) less effective, leading to higher fever.

"Small doses of Atropine or scopolamine inhibit the activity of sweat glands, despite the vasodilatation the drug may cause in some skin areas. The skin becomes hot and dry, sweating may be depressed enough to raise the body temperature. Nevertheless, in infants and small children moderate doses induce 'atropine fever'... Suppression of sweating is doubtless a considerable factor in the production of the fever, especially when the environmental temperature is high..."^{3,1}

USED : Analgesics for pain, anti-pyretics for fever. Atropine as an anti-spasmodic and as an antidote to certain poisons, like organophosphorus insecticides.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED :

NEPAL^{3*}

SAFER ALTERNATIVES: Painkiller (eg. aspirin) or fever reducer (eg. paracetamol) without atropine, or atropine alone.

4. FIXED DOSE COMBINATIONS OF STRYCHNINE AND CAFFEINE IN TONICS

This combination was available until 1985.

REASON FOR BANNING: Dangerous. Strychnine has no useful effect, and too much can cause convulsions and death. Caffeine is not useful in tonics, and is usually included in

^{3,1} Goodman & Gilman, "The Pharmacological Basis of Therapeutics (Quoted) 7th Ed. 1985. P136.

^{3*} The fact that a given product is not listed as banned or restricted by a country does not necessarily mean that it is permitted in that country.

Countries which have never allowed these drugs, and therefore do not need to ban them, are not listed here. Other countries (also not listed) have a legal structure which discourages the introduction of hazardous or irrational drugs.

subtherapeutic (insufficient) doses.

“Strychnine has no demonstrated therapeutic value, despite a long history of unwarranted popularity”.^{4.1}

“There is no rational basis for the use of strychnine in therapy and therefore, no justification for the use of it in any proprietary medicine. There is a very narrow margin between the therapeutic dose and the toxic dose of strychnine”.^{4.2}

See page for details on Gazette Ambiguities.

USED : Caffeine and strychnine are used as stimulants. (Strychnine is considered obsolete as regards the therapeutic value).

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:

Bangladesh, Canada, Italy, Nepal, Philippines and Turkey.

SAFER ALTERNATIVES: Omission of strychnine or caffeine, or better still, provision of nutritious food. As a stimulant, the therapeutic dose of caffeine is 100 mg. (e.g. 2 cups of coffee).^{4.3}

5. FIXED DOSE COMBINATIONS OF YOHIMBINE AND STRYCHNINE WITH TESTOSTERONE AND VITAMINS

Drugs containing yohimbine, strychnine,

testosterone and vitamins together are not listed in MIMS, CIMS and Pharmaceutical Guide. Their presence in the market cannot be commented upon. (Those containing yohimbine and strychnine separately are listed under gazette Ambiguities on page 79).

6. FIXED DOSE COMBINATIONS OF IRON WITH STRYCHNINE, ARSENIC AND YOHIMBINE

Drugs containing iron, strychnine, arsenic and yohimbine together are not listed in MIMS, CMS or Pharmaceutical Guide. Their presence in the market cannot be commented upon. Those containing strychnine, arsenic and yohimbine separately are listed under ‘Gazette Ambiguities’.

7. FIXED DOSE COMBINATIONS OF SODIUM BROMIDE/ CHLORAL HYDRATE WITH OTHER DRUGS

REASON FOR BANNING: Dangerous. Sodium bromide can cause vomiting, dizziness and hallucinations. Chloral hydrate can cause stomach irritation, nightmares and confusion. Their therapeutic concentration in the blood is very close to their toxic levels and there are safer hypnotic drugs today, so they are now obsolete.

“Bromides were formerly used for their sedative and anti-convulsant properties; they have been replaced by more effective and less toxic drugs”.^{7.1}

4.1. Goodman & Gilman. The Pharmacological Basis of Therapeutics 7th edition, 1985. p. 584.

4.2. Drug Consultative Committee recommendations 1980

4.3. Martindale : The Extra Pharmacopia. 28th edition, P. 340

7.1. Martindale : The Extra Pharmacopia. 28th edition, P. 338. (Quoted)

"In therapeutic doses side-effects of (chloral hydrate) include gastric irritation, light headedness, ataxia, nightmares, excitement and confusion (sometimes with paranoia)".^{7,2}

USED: As sedative

8. PHENACETIN/ACETOPHENE-TIDIN/PHENACETINIUM/ACETOPHENETIDIDE

REASON FOR BANNING: Dangerous. Can cause liver and kidney damage, Safer alternatives available, therefore obsolete.

"Prolonged administration of large doses of analgesic mixtures containing phenacetin, has been associated with the development of renal papillary necrosis' and appears to be associated with the development of transitional-cell carcinoma of the renal pelvis. Phenacetin has analgesic and antipyretic actions similar to those of aspirin".^{8,1}

"Fixed dose combinations of any category of drugs with phenacetin should not be allowed, as the question of banning phenacetin because of its potential toxicity (nephropathy, methemoglobinemia, hemolytic anemia as a consequence of chronic overdosage) is under active consideration of the Government."^{8,2}

USED: For pain, inflammation and fever.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:

Canada, Chile, Cyprus, Denmark, Finland, Israel, Italy, Mauritius, Nepal, Nicaragua, Norway, New Zealand, Philippines, Rumania, Saudi Arabia, Sweden, Thailand, Turkey, U.K., U.S.A., Yemen.

SAFER ALTERNATIVES: For fever: paracetamol, for pain and inflammation: aspirin.

9. FIXED DOSE COMBINATIONS OF ANTI-HISTAMINICS WITH ANTI-DIARRHOEALS

This combination was available until 1984.

REASON FOR BANNING : Dangerous. The anti-histaminic action may mask other symptoms and make accurate diagnosis and treatment difficult.

USED: Anti-histaminics for allergies; anti-diarrhoeals for diarrhoeas

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:

Nepal^{9*}

7.2. Martindale : The Extra Pharmacopia. 28th edition, P. 396. (Quoted)

8.1. Ibid. P.271

8.2. Drug Consultative Committee Recommendation, 1980.

9.* The fact that a given product is not listed as banned or restricted by a country does not necessarily mean that it is permitted in that country.

Countries which have never allowed these drugs, and therefore do not need to ban them, are not listed here. Other countries (also not listed) have a legal structure which discourages the introduction of hazardous or irrational drugs.

10. FIXED DOSE COMBINATIONS OF PENICILLIN AND SULPHONAMIDES

This combination was available until 1985.

REASON FOR BANNING: Dangerous. Penicillin is bacteriocidal (kills bacteria), whereas sulphonamides are bacteriostatic (stop bacteria multiplying), so the combination may diminish the bactericidal effects of penicillins, making them useless.

“Fixed dose combinations of penicillin with sulphonamides are irrational for the following reasons:

a) The combination of penicillin, a bactericidal drug and sulphonamides a bacteriostatic drug, may cause antagonism.

b) There is a risk of development of bacterial resistance to both the drugs.”^{10.1}

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:

Nepal.

SAFER ALTERNATIVES: Penicillin or Sulphonamide, not both.

11. FIXED DOSE COMBINATIONS OF VITAMINS WITH ANALGESICS

REASON FOR BANNING: Irrational, vitamins are not painkillers, analgesics do not

help in the treatment of vitamin deficiency. Combining the two only leads to unnecessary cost.

“Fixed dose combinations of high dose vitamins with analgesics should not be allowed unless there is adequate evidence in support of the rationale of such combination.”^{11.1}

USED: Analgesics for pain, vitamins for vitamin deficiency.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED:

Bangladesh, Philippines.

RATIONAL ALTERNATIVE: Pain killer alone: or vitamins (from nutritious food if possible) for vitamin deficiency.

✓ 12. FIXED DOSE COMBINATIONS OF TETRACYCLINE/VITAMIN C

Brand	Manufacturers
TETRAMYCIN S.F.	Pfizer

REASON FOR BANNING: Irrational. Vitamin C does not help in the treatment of diseases requiring tetracycline, it only increase the cost of the drug. See also Nos 19 and 24 on pages 47 and 48.

USED: For bacterial infection.

EXAMPLE OF COMBINATIONS: Terramycin SF Cap. (Pfizer) : Oxytetracycline hel., Vitamin C, Vitamin B1, Vitamin B2, Niacinamide, Cal. Pantothenate, Vitamin B6,

10.1. Drug Consultative Committee recommendations 1980.

11.1. Drug Consultative Committee recommendations 1980. Now reformulated: Check label for contents.

Folic acid Vitamin B12.

**COUNTRIES WHERE BANNED,
WITHDRAWN OR RESTRICTED:**

Italy, Nepal, Sweden, USA, Venezuela.

RATIONAL ALTERNATIVE: Tetracycline alone (for men and non-pregnant and non-lactating women only - see 19 and 24 on pages 47-48 on Oral Tetracycline). Another antibiotic for pregnant or lactating women, and children.

**13. FIXED DOSE COMBINATIONS
OF HYDROXYQUINOLINE
GROUP OF DRUGS EXCEPT
PREPARATIONS WHICH ARE
USED FOR THE TREATMENT OF
DIARRHOEA AND DYSENTRY
AND FOR EXTERNAL USE ONLY.**

All hydroxyquinoline (clioquinol) drugs on the market are intended for either diarrhoea or for external use. See also no. 50 on page 60.

**14. FIXED DOSE COMBINATION
OF STEROIDS FOR INTERNAL
USE EXCEPT COMBINATIONS
OF STEROIDS WITH OTHER
DRUGS FOR TREATMENT OF
ASTHMA.**

REASONS FOR BANNING: Dangerous, steroids are powerful drugs and should only be used in carefully individualized doses, starting with a "loading dose" and then tapering off.

Fixed dose combinations do not allow this tapering off, prescribers, dispensers and patients are very often unaware that a combinations contains a steroid, so that the drug if stopped abruptly leads to fall in blood pressure and kidney problems. Combinations of steroids with other drugs is irrational.

Fixed dose combinations of steroids with any other category of drugs should not be allowed as they are considered harmful for the reasons.

If the steroid is abruptly withdrawn, the adrenal suppression accompanying steroid therapy leads to symptoms and signs of adrenal insufficiency.

It is difficult to adjust the dose of the steroid when it is present in fixed dose combinations with other drugs^{14.1}.

Emperical use of Corticosteroids may mask the symptoms to such an extent that a true diagnosis becomes extremely difficult to make^{14.2}.

Fixed dose combination of steroids for asthma had been excluded by the Drug Technical Advisory Board even though the Drug Consultative in 1980. The result had been that suddenly indication of steroid combinations e.g. Cortopen, Betaklor Contimal etc. had changed from allergy, insect bites, food poisoning etc. to be bronchial asthma.

Hence most of the drugs that should have been banned had escaped the ban while the

14.1 Drug Consultative Committee Recommendations 1980.

14.2 Martindale 30th Edn. 1993 pg.714.

misuse continued^{14.3 & 14.4}.

14*. FIXED DOSE COMBINATION OF CORTICO STEROIDS WITH ANY OTHER DRUG FOR INTERNAL USE WAS BANNED IN 1988

(No.14 of Gazette Notification Banned Drug List)

Brand	Manufacturer	Contents
Docabolin	Infar	Nandrolone- phenylpro- pionate, desoxycorti- costerone phenylpropio- nate.

Steroid + antihistaminic

Brand	Manufacturer	Contents
Cortomin	Systopic	Betamethasone
Cyproheptadine c Dexamethasone	Tablets Ind. Ltd	—
Betamin S	Chemitech Drug	Betamethasone Chlorphenisame
Stemin	Ind Swift	Betamethasone Chlorphenisame

REASONS FOR BANNING: Two categories of Toxic effects are observed in the therapeutic use of adrenocorticoids: those resulting from withdrawal and those resulting from continued use of large doses.

Acute adrenal insufficiency results from too rapid withdrawal of corticosteroids after prolonged therapy.

A characteristic corticosteroid withdrawal syndrome, consisting of fever, myalgia, arthralgia and malaise, may be extremely difficult to distinguish from reactivation of rheumatoid arthritis or rheumatic fever (Amatruda et al 1960).

Pseudotumor cerebri and papilledema is a rare reaction that follows reduction or withdrawal of Corticosteroid therapy (i.e. increase in intracranial tension) (Levine & Leopold, 1973).

Processes of recovery of normal pituitary and adrenal function required 9 months in some patients.

During this recovery period and for an additional 1 or 2 years, the patient may need to be protected during stressful situations, such as surgery or severe infections, by the administration of Corticosteroids.

In addition to pituitary-adrenal suppression, the principal complications resulting from prolonged therapy with corticosteroids are fluid and electrolyte disturbances; hypertension; hyperglycemia and glycosuria; increased susceptibility to infections, including tuberculosis; peptic ulcers, which may bleed, perforate; osteoporosis; a characteristic myopathy; behavioural disturbances; posterior sub-capsular cataracts; arrest of growth; Cushing's habitus consisting of "moon face" "buffalo hump", enlargement of supraclavicular fat pads, "central obesity"

14.3. Rational Drug Policy VHAI-AIDAN 1986 Pg.

14.4. Rational Selection of Drugs VHAI 1986 Pg. (International Consultation)

striae, ecchymoses, acne and hirsutism.

Myopathy characterised by weakness of the proximal musculature of arms & legs and legs of their associated shoulder and pelvic muscles, is occasionally seen in patients taking large doses of corticosteroids.

It may occur soon after treatment is begun and be sufficiently severe to prevent ambulation.

Behavioural disturbances may take various forms including nervousness, insomnia, changes in mood or psyche, & psychopathies of the manic depressive or schizophrenic type. Suicidal tendencies are not uncommon.

Posterior sub-capsular cataracts have been reported in children receiving corticosteroid therapy.

Osteoporosis and vertebral compression fractures are frequent serious complications of corticosteroid therapy in patients of all ages.

Rib & vertebrae, bones with a high degree of trabecular structure, are generally the most severely affected.

Unfortunately, significant loss of bone must occur before it is apparent from radiography.

Aseptic necrosis of bone (Osteonecrosis) may complicate long term therapy with glucocorticoids and has also been reported

following short courses with high doses: The femoral head is most often involved, but other large joints may be affected, joint pains and stiffness may be the earliest symptoms and the syndrome.

Inhibition or arrest of growth can result from administration of relatively small doses of glucocorticoids to children and it cannot be overcome with exogenous human growth hormone.^{14*1}

Fixed dose combinations of steroids should not be allowed because, if the steroid is abruptly withdrawn, the adrenal suppression accompanying prolonged steroids therapy leads to symptoms of adrenal insufficiency. It is difficult to titrate the dose of the steroid when it is present in fixed dose combination with other drugs.^{14*2}

Concurrent administration of corticosteroids will cause excessive loss of potassium.^{14*3} Also it is impossible to vary the dosage or time schedule of each drug separately. If adverse effects arise it is difficult to know which drug is responsible for them.^{14*4}

Corticosteroids and androgens affect the protein bound iodine.^{14*5}

In addition to pituitary-adrenal suppression, the principal complications resulting from prolonged steroid therapy are: fluid and electrolyte disturbances, hyperglycemia and glycosuria, increased

14*.1. Goodman & Gilman. The Pharmacological Basis of Therapeutics 8th Edn. Vol II 1991 P. 1448-1452

14*.2. Drug Consultative Committee Recommendations 1980.

14*.3. Martindale Entrapharmacopea 28th Edn. 1982 P. 449.

14*.4. Parish P. medicines - a guide for everybody 5th Edn. 1984. P. 29.

14*.5. Adverse Drug Reaction Bulletin 1972 Jame P., P. 104.

susceptibility to infections including tuberculosis, peptic ulcers (which may bleed or perforate), osteoporosis, a characteristic myopathy, behavioural disturbances, and Cushing's habitus, consisting of "moon face", "buffalo hump", enlargement of supra clavicular fat pads, acne etc.^{14*.6}

Unless considered life saving, systemic administration of corticosteroid is contraindicated in patients with peptic ulcers, osteoporosis, psychoses, or severe psychoneurosis and they should be used only with great caution in the presence of congestive heart failure in patients with diabetes mellitus, infectious diseases, chronic renal failure and uraemia, and in elderly persons. Empirical use of Corticosteroid may mask the symptoms to such an extent that a true diagnosis becomes extremely difficult to make.^{14*.7}

COUNTRIES WHERE BANNED, WITHDRAWN OR SEVERELY RESTRICTED:

Bangladesh, Turkey, Denmark, Saudi Arabia, Venezuela, Italy, Australia, Belgium, Greece, Norway, New Zealand, Singapore, Thailand, USA, India, Nepal, etc.^{14*.8}

SAFER ALTERNATIVES: Single steroid drug whenever needed.

15. FIXED DOSE COMBINATION OF CHLORAMPHENICOL FOR INTERNAL USE EXCEPT COMBINATIONS OF

CHLOROAMPHENICOL AND STREPTOMYCIN (1983).

REASON FOR BANNING: Changes in the peripheral blood include leukopenia, (decrease in white cell count) thrombocytopenia (decrease in platelet count) and aplasia of the bone marrow with fatal pancytopenia (fall in number of red cells, white cells and platelets)

Resistance to chloramphenicol in *S. Typhi* has become a worldwide problem.

Used in Typhoid (Enteric fever)

Paratyphoid and misused trivial infections and bacterial diarrhoea.

COUNTRIES WHERE BANNED WITHDRAWN OR RESTRICTED:

Egypt, Italy, Japan, Nepal and Phillipines.

SAFER ALTERNATIVES: Cotrimoxazole, ampicillin and other antibiotics depending upon the cause.

15*. FIXED DOSE COMBINATION OF CHLORAMPHENICOL WITH ANY OTHER DRUG FOR INTERNAL USE WAS BANNED IN 1988

No.15 in the Banned Drug List of Gazette Notification, (3rd November) 1988.

REASON FOR BANNING: Dangerous. Chloramphenicol can cause fatal

14*.6. Goodman & Gilman 8th Edn. 1991 p.1448.

14*.7. Martindale, 30th edn. 1993 p. 714.

14*.8. Consolidated List of Products: United Nations Secretariat 37/137, 1986.

agranulocytosis^{15*1} and should therefore be used only when it is specifically indicated (eg. for typhoid). Of all the drugs that may be responsible for pancytopenia, chloramphenicol is the most common cause. These reactions may represent an idiosyncratic reaction to the drug. The incidence is not related to dosage, however it seems to occur more commonly in individuals who undergo prolonged therapy and especially in those who are exposed to the drug on more than one occasion.^{15*2}

“(Chloramphenicol) should never be employed in diseases readily, safely and effectively treatable with other antimicrobial agents, or in undefined situations”.^{15*3}

Often serious blood dyscrasias including aplastic anaemias after both short term and prolonged therapy, bone marrow suppression, grey baby syndrome in infants, G.I. upsets, optic and peripheral neuritis and allergic skin reactions can be caused by chloramphenicol. Resistance to Chloramphenicol in *S Typhi* has become a worldwide problem.^{15*4}

Chloramphenicol may interfere with development of immunity and it should not be given during active immunization:

Streptomycin is used for treating tuberculosis. The combination is therefore not useful at all, and only leads to the unnecessary

consumption of either chloramphenicol or streptomycin, so that strains of TB become resistant to the latter, thus rendering the drug useless for TB.

Streptomycin is a drug of choice in the treatment of tuberculosis and should generally be reserved for this use because when used in the treatment of other bacterial infections resistance has been found to develop within 2 to 3 days.

The combination of chloramphenicol with streptomycin was recommended for weeding out by the Subcommittee of Drug Consultative Committee in 1980 for the following reason:

Fixed dose combinations of chloramphenicol with streptomycin should not be allowed. As chloramphenicol is potentially a toxic drug, its use should be kept restricted to enteric fever only”.

This combination was excluded from the Banned Drug List by the Drug Technical Advisory Board in 1982 and by the Gazette Notification of Drug Controller of India, 23rd July, 1983 (P.5).

It was later banned under the Gazette Notification of 3rd November, 1988.

USED: for diarrhoea and amoebic dysentery.

15*.1. See glossary

15*.2. Goodman & Gilman. The Pharmacological Basis of Therapeutics. 8th edition. 1991. P. 1127

15*.3. Goodman & Gilman. The Pharmacological Basis of Therapeutics. 8th edition. 1991. P. 1129

15*.4. Ibid. 7th edition P. 1183.

EXAMPLE OF COMBINATIONS:

Brand	Manufacturer
Aurostrep	Aurochem
Enterostrep	Dey's
Wexostrep	Jhones & Wexoes

(From Indian Pharmaceutical Guide 1993)

COUNTRIES WHERE BANNED WITHDRAWN OR RESTRICTED.

Bangladesh, Cyprus, Denmark, Dominican Republic, Italy, Japan, Nepal, Norway, Philippines, Saudi Arabia, Sweden, Venezuela, Sri Lanka, Pakistan and Malaysia.

SAFER ALTERNATIVE: For diarrhoea, oral rehydration therapy; for amoebic dysentery, oral rehydration therapy and metronidazole; for bacillary dysentery - appropriate antibiotic along with oral rehydration therapy should be given.

16. FIXED DOSE COMBINATIONS OF ERGOT

Brand	Manufacturer
Migril	B. Wellcome
Vasograin	Cadila

REASON FOR BANNING: Dangerous and irrational. Ergotamine is useful for migraine headache, and ergometrine for haemorrhage after child birth, but they should be used very carefully in the minimum dose required, since overdose leads to gangrene and loss of limbs. Caffeine taken with ergotamine enhances the effects of ergotamine, but a fixed-dose combination is unnecessary. Prophylactic (preventive) use is hazardous because of the risk of overdose leading to gangrene.

"The usual dose (or ergotamine) is 1-2 mg. administered by mouth...Not more than 6 mg. should be administered in a day and not more than 10 mg. in a week"^{16.1}

"The ergot alkaloids are highly toxic and may cause acute or chronic poisoning...Poisoning is usually due to overdose."^{16.2}

USED: Ergotamine for migraine and vascular headache; ergometrine for severe bleeding after child birth.

SAFER ALTERNATIVES: Ergotamine or ergometrine alone, in correct doses, course of Propranolol under Medical Guidance.

17. FIXED DOSE COMBINATIONS OF VITAMINS WITH ANTI-TB DRUGS EXCEPT COMBINATIONS OF ISONIAZIDE WITH PYRIDOXINE HYDROCHLORIDE (VIT.B6)

REASON FOR BANNING: Irrational. Isoniazide has an anti-vitamin B6 effect, therefore supplementary vitamin B6 is required when treatment includes isoniazid. This is not so for other anti-TB drugs.

USED: For tuberculosis.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED : None

RATIONAL ALTERNATIVE: TB drugs alone, or with Vitamin B6 if isoniazide is used.

16.1. Goodman & Gilman, The Pharmacological Basis of Therapeutics, 7th edition, 1985, P. 937.

16.2. Quoted James Whang, The Essential Guide to Prescription Drug, 8th edition, 1985, P. 773.

18. PENICILLIN SKIN/EYE OINTMENT

As far as we are able to discover, penicillin skin/eye ointment is not listed as available in the Indian market.

19. TETRACYCLINE/LIQUID ORAL PREPARATIONS

(See also no. 24, P. 48)

REASON FOR BANNING: Children receiving long or short term therapy with a tetracycline may develop brown discolourations of the teeth. Treatment of pregnant women with tetracycline may produce discolouration of the teeth in their offspring.

“Tetracyclines are deposited in the skeleton during gestation and throughout childhood. A 40% depression of bone growth has been demonstrated in premature infants treated with these agents”.^{19 1}

USED: For bacterial infections.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Bangladesh, Denmark, Italy, Jordan, New Zealand, Peru, Philippines, Saudi Arabia.

SAFER ALTERNATIVES: (For children and lactating or pregnant (women) another antibiotic.

20. NIALAMIDE

REASON FOR BANNING: Severe hypertensive reactions, sometimes fatal, may occur if given simultaneously with some other drugs or cheese and certain other foods.

As far as we are able to discover, nialamide is not listed as available in the Indian market.

21. PRACTOLOL

REASON FOR BANNING: Serious adverse effects on the skin, eyes, oral and nasal mucous membranes, and peritonium have been associated with practolol therapy. The changes are associated with immunological disturbances.

As far as we are able to discover, practolol is not listed as available in the market.

22. METHAPYRILENE, ITS SALTS

Methapyrilene was available in the market until 1984.

REASON FOR BANNING: Dangerous. Can cause cancer, and there are much safer alternatives.

“It is less potent than promethazine and has a much shorter duration of action”.^{22 1}

19.1. Goodman & Gilman. The Pharmacological Basis of Therapeutics. 8th edition. 1991. P. 1122

22.1. Martindale. The Extrapharmacopia 28th Edn. P. 1315.

USED: For inducing sleep and as an antihistaminic.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Australia, Canada, Chile, Dominican Republic, Italy, New Zealand, Philippines, Singapore, UK, USA, Venezuela, West Germany.

SAFER ALTERNATIVES: Other antihistaminic or sleep inducing agents.

23. METHAQUALONE

(Banned under GSR 49(E) dated January 31, 1984).

REASON FOR BANNING: Risk of abuse and severe intoxication due to overdose, including lethal intoxication.

USED AS: Narcotic Psychotropic.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Greece, Italy, Norway, Sweden, Venezuela.

24. OXYTETRACYCLINE LIQUID ORAL PREPARATIONS

(Banned May 3, 1984 GSR 322 (E)) Dealt with earlier no.19 on P.

REASON FOR BANNING: Oxytetracycline Demeclocycline liquid oral preparations Tetracyclines are deposited in deciduous and permanent teeth causing discoloration, enamel hypoplasia and reduced mineralisation. They are also deposited in calcifying areas in bone and the nails and when given in therapeutic doses to young infants or women during the later stages of pregnancy

tetracyclines interfere with bone growth. An increase in intracranial pressure, which may be associated with a bulging fontanelle in infants has been reported in patients given tetracyclines.

25. DEMECLOCYCLINE LIQUID ORAL PREPARATION

(No drugs formulations in the market)

REASON FOR BANNING: Oxytetracycline Demeclocycline liquid oral preparations Tetracyclines are deposited in deciduous and permanent teeth causing discoloration, enamel hypoplasia and reduced mineralisation. They are also deposited in calcifying areas in bone and the nails and when given in therapeutic doses to young infants or women during the later stages of pregnancy tetracyclines interfere with bone growth. An increase in intracranial pressure, which may be associated with a bulging fontanelle in infants has been reported in patients given tetracyclines.

26. COMBINATIONS OF ANABOLIC STEROIDS WITH OTHER DRUGS

REASON FOR BANNING: Combination of anabolic steroid with other drugs. Testosterone and other androgens give rise to side effects which can be related to their androgenic or anabolic activities. They include increase in nitrogen retention and skeletal weight, sodium and water retention, oedema, increased vascularity of skin, hypercalcaemia, and increased growth of the bone. Large and repeated doses in early puberty may cause closure of epiphyses and stop linear growth.

Elderly males may become overstimulated. Continued administration of large doses produces symptoms of virilism, such as male pattern hirsutism, deepening of the voice, atrophy of the breasts, and endometrial tissue, acne, and hypertrophy of clitoris, libido is increased and lactation suppressed.

The only indication for anabolic steroids is in the treatment of some aplastic anaemias and to reduce the itching of chronic biliary obstruction (in terminal care) and as such its combination with other drugs has no justification.

Brand	Manufacturer
Docabolin	Infar
Mixogen	Infar

(See also page 55)

27. HIGH DOSE ESTROGEN PROGESTERONE COMBINATION DRUGS

Banned under No.X 11018/1/88/DMS & PFA Gazette Notification of 15th June 1988. (No.20 in the banned drug list.)

REASON FOR BANNING: Dangerous, increased risk of birth defects if taken by pregnant women. There is no indication for high dose oestrogen-progesterone combinations in gynaecology and obstetrics.

"A substantial proportion of women who are not pregnant will have their menses delayed by the administration of the hormone".^{27.1}

"Normal treatment for secondary amenorrhoea: 10-20 mg oral norethisterone (weekly)."^{27.2}

"These (hormonal pregnancy) tests should no longer be done."^{27.3}

"Hormonal tests for pregnancy are not reliable. The test is false positive in one out of five women. There is also an increased risk of abnormalities."^{27.4}

"Pregnant patients should not be given estrogens, particularly during the first trimester- a time when the foetal reproductive tract is developing and may be influenced by exogenous estrogens."

Hormonal pregnancy test is not only unreliable but should be condemned because of possible teratogenic effect of the progestogen used.^{27.5}

In a study of the 52 mothers who had given birth to babies with congenital birth defects 31% had taken hormonal preparation during early pregnancy often with a view of terminating it.^{27.6}

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- 27.1. WHO Technical Report Series No. 657, 1981
 - 27.2. Ibid. P. 9
 - 27.3. Ibid. P. 62
 - 27.4. D. Vengada Salan et al JOG 14:348-253, 1976
 - 27.5. Dr. D.C. Dutta. Text book of Obstetrics P. 73
 - 27.6. Dr. B. Palaniappen, Kilpauk Medical College, 1975
-

High dose estrogen progesterone hormonal combinations used to test the presence of pregnancy cause birth defects in high percentage of cases. This was reported in a study of the congenitally malformed babies born amongst 4291 deliveries. The study was conducted between March 1981 to February 1982 at R.N.T. Medical College, Zanana Hospital, Udaipur by Dr. M.A. Abbas.

Teratogenic effects on the unborn foetus have been observed by various researchers when the high dose Estrogen Progesterone Combination has been taken during pregnancy Spina bifida (Dr. I. Gal)^{27.7}, CNS defects (Greenberg)^{27.8}, Cardiac defects (Dr. Arcy and Greffin), congenital heart disease^{27.9} Vactreal (Vertebral, Anal, Cardiac, Tracheal, Oesophageal, Renal and Limb Defect)^{27.10} Limb defect (Janerich).

There is no role for high dose estrogen progesterone combinations in gynecological practice as therapeutic agents or as diagnostic tests.^{27.11}

There is no justification for the use of high dose EP drugs in amenorrhoea, menstrual irregularity and gynaecological disorders.^{27.12}

Only a small percentage of women with secondary amenorrhoea require hormonal preparations since in India the major cause of

secondary amenorrhoea are malnutrition, anaemia, tuberculosis and psychological stress. With the advent of oral contraception, it is more appropriate to use sequential oral contraception as substitution therapy for secondary amenorrhoea.^{27.13}

The EP drugs case has highlighted the denial of warnings about possible teratogenic effects on unborn foetus of medicines prescribed and consumed during pregnancy, especially in the first trimester.

Submissions made during the 4 hearings on EP case with arguments and views, research studies as to why the drug should be banned are available.

USED: These drugs have been used for secondary amenorrhoea when oestrogen - progesterone hormonal deficiencies are suspected or have been diagnosed.

In India in reality these drugs are mainly misused for attempting to induce abortion and for hormonal pregnancy testing.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Austria, Belgium, Denmark, Greece, Italy, New Zealand, Norway, Singapore, Saudi Arabia, South Africa, Thailand, U.K., U.S.A., Venezuela, West Germany.

27.7. Nature London 216, 83 (1967)

27.8. Greenberg and Coworkers Hormonal pregnancy tests & congenital malformation, British Medical Journal, 2.191-2 (1975)

27.9. Heininen and coworkers Cardiovascular birth defects and ante natal exposure to female sex hormones-New England, Journal of Medicine, 296 67-70.

27.10. Harlap and coworkers Birth Defects and Gestogen and Progestones in Pregnancy-Lancet 1.682-3.

27.11. Prof. M.S. Rawlins, Prof. Clinical Pharmacology, University New Castle upon Tyne.

27.12. Dr. Stephen Franks, St. Mary's Hospital, Medical School of London.

27.13. J.R. Newton, Novak's Textbook of Gyneacology 10th Edn., P. 260.

SAFER ALTERNATIVE: Appropriate treatment after diagnosis of cause of secondary amenorrhoea. (eg. anaemia, malnutrition, stress, tuberculosis etc.)

For secondary amenorrhoea: cyclical use of estrogen and progesterone separately or use of oral contraceptives for approximately 3 cycles.

For pregnancy testing: urine test (human chorionic gonadotropin detection in urine). Clinical examination and confirmation of pregnancy based on known and well recognised physiological changes of pregnancy.

See P.96 for details.

28. FIXED DOSE COMBINATION OF SEDATIVES/HYPNOTICS/ ANXIOLYTICS, WITH ANALGESIC ANTIPYRETIC.

REASON FOR BANNING : Analgesics are conveniently divided into two groups depending upon their efficacy. These are simple analgesics and narcotic analgesics. Simple analgesics are indicated for relief of mild pain or moderate pain and also as antipyretics. As such, there is no need of making a combination with sedative/hypnotic or anxiolytic. For severe pain, narcotic analgesics are available and there is no need to add sedatives and analgesics. Sedatives/hypnotics/anxiolytics may mask the symptoms by inducing sleep. They are habit forming and the paediatric forms may lead to accidental overdose.

Fixed dose combinations do not give the liberty of dosage according to weight.

29. FIXED DOSE COMBINATION OF PYRAZINAMIDE WITH

OTHER ANTI-TUBERCULAR DRUGS EXCEPT COMBINATION AND INH AS PER RECOMMENDED DAILY DOSE GIVEN BELOW:

Drugs	Maximum	Minimum
Rifampicin	450 mg	600 mg
INH	300 mg	400 mg
Pyrazinamide	1000 mg	1500 mg

REASON FOR BANNING : Major cause of tubercular treatment failure are incorrect prescribing by the physician and inadequate compliance by the patient. Avoid both excessive and inadequate dosage. Treatment should be supervised by a specialist physician (BNF no. 28 sept. 94 pg. 240)". By fixing the dosages, the wrong dosages can be avoided. Inadequate, small doses are likely to increase drug resistant tubercular bacilli.

Brand	Manufacturer	Contents in mg.		
		Rif.	INH	Pyr.
Monotrip	Plethico	150	100	500
Rifater	Tata	120	80	250
Rinizid	Lupin Div II	150	100	375
Tricox	Themis Chem	150	100	500

30. FIXED DOSE COMBINATION OF HISTAMIN H2 RECEPTOR ANTAGONIST WITH ANTACIDS EXCEPT FOR THOSE COMBINATIONS APPROVED BY THE DRUG CONTROLLER OF INDIA.

REASON FOR BANNING : FDC of histamine H2 receptor antagonist with antacids.... Antacids are best given one hour after food when gastric activity is at its peak.

Antacids are likely to absorb other drugs including ulcer healing drugs and reduce their efficacy.

(This is an ambiguous form of Gazette Notification from which one does not know which drug combinations are approved by the Drug Controller of India).

Brand	Manufacturer	Contents
Tricaine-MPS	Searle	Oxymethazine, MPS, Aluminium hydroxide, Magnesium hydroxide Gel.

31. THE PATENT AND PROPRIETARY MEDICINES OF FIXED DOSE COMBINATIONS OF ESSENTIAL OILS WITH ALCOHOL HAVING PERCENTAGE HIGHER THAN 20 PERCENT PROOF EXCEPT PREPARATIONS GIVEN IN THE INDIAN PHARMACOPOEIA.

REASON FOR BANNING : Alcohol interacts with many important drugs and enhances the sedative/hypnotic effects of analgesic antidepressants, anti histamines, antimuscaranics, antipsychotics, anxiolytics and hypnotics, muscle relaxants enhance the hypotensive effects of drugs like analgesics, antihypertensives, beta-blockers and nitrates, enhances hypoglycemic effects of antidiabetic drugs, enhances side effects of antiepileptics. The feeling of well being is very transient and addition of alcohol has no other long term

advantage.

32. ALL PHARMACEUTICAL PREPARATIONS CONTAINING CHLOROFORM EXCEEDING 0.5% W/W OR V/V, WHICH EVER IS APPROPRIATE.

REASON FOR BANNING : Chloroform is hepatotoxic and nephrotoxic. It depresses respiration and produces hypotension. Cardiac output is reduced and arrhythmias may develop. Chloroform in a concentration of 0.2% is a useful preservative for extemporaneously prepared mixtures but doubts have been cast on the safety of the long term use of chloroform in mixtures and toothpastes.

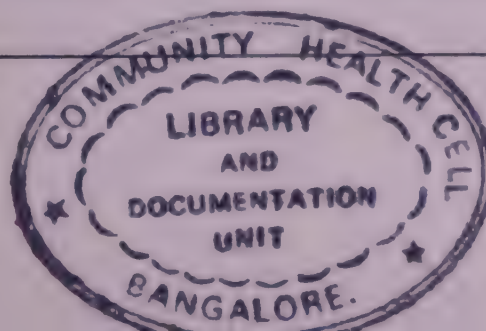
Brand	Manufacturer	Contents
Deacos	IDPL	Chloroform 18.5 mg/5ml
Dristan Expectorant	Wyeth	Chloroform 0.0125/5ml

33. FIXED DOSE COMBINATION OF ETHAMBUTOL WITH INH OTHER THAN FOLLOWING:

INH 200 mg + ethambutol 600 mg
INH 300 mg + ethambutol 800 mg

REASON FOR BANNING : Side effects of ethambutol are largely confined to visual disturbances in the form of loss of acuity, colour blindness and restrictions of visual fields. The earliest feature of ocular toxicity are subjective and patients should be advised to discontinue therapy immediately if they develop deterioration in vision and promptly seek

DR-410
N96
0399



further advice. As such, a fixed dose combination with INH is not suitable for immediate discontinuation.

Brand	Manufacturer	Contents
Myconex 600	Cadila	INH 300 mg + Ethambutal 600 mg

34. FIXED DOSE COMBINATION OF ANTIHELMINTIC, CATHARTIC/PURGATIVES EXCEPT FOR PIPERAZINE.

REASON FOR BANNING : Most of the antihelminthics have side effects viz. Abdominal pain, diarrhoea, etc and as such there is no need of cathartic or purgatives along with them.

35. FIXED DOSE COMBINATION CONTAINING MORE THAN ONE ANTI-HISTAMINIC

REASON FOR BANNING : FDC of more than one antihistaminic. There is no evidence that anyone of the older, sedative antihistaminics is superior to any other and patients vary widely in their responses. There is no synergistic or additive effect of antihistamines, and as such FDC of more than one antihistaminic is not advisable.

Brand	Manufacturer
Alernyl Exp.	Sigma
Tristina	MAC

36. FIXED DOSE COMBINATION OF SALBUTAMOL OR ANY OTHER BRONCHODILATOR

WITH CENTRALLY ACTING ANTI-TUSSIVE AND/OR ANTI-HISTAMINE.

REASON FOR BANNING : According to BNF (British National Formulary brought out annually) there is no evidence that any drug can specifically facilitate expectoration. For this reason, expectorant cough medicines have been described as "an expensive myth". Therefore there is no rationale for their use.

The drawbacks of prescribing cough suppressants are rarely outweighed by the benefits of treatment and only occasionally are the useful, as for example, if sleep is disturbed by a dry cough. Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis. Though commonly used in acute bronchitis and pneumonia, they can be harmful; such conditions are best treated by prompt administration of antibacterial drugs. Cough suppressants such as codeine, dextromethorpan and pholcodine are seldom sufficiently potent to be effective and all tend to cause constipation. The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children and should be avoided altogether in those under one year of age.

Compound cough preparations have no place in the treatment of respiratory disorders, and such preparations are to be deprecated not only as irrational but also for leading to patients receiving inappropriate drugs. See also No. 39-40, P. 55 and 56..

Cough Mixtures with ephedrine, antihistaminic, analgesic etc.

Brand	Manufacturer	Mucof Exp	Aurochem
Actifed	B. Welcome	Naskaf	Lancet
Bena Fedrin	Parke Davis	Nu-Hicolin Exp	T.M. Thakore
Bronyl	Pans	Novafed Tablet	Welbeck
Broxex	Docman	Ociphylin	Universal
Bronolax	Alkem	Osadyl	Osaka
Cophedrin	Acron	Protusa plus cough	Boots
Cemdri exp	Beckcem Drug Int.	Pedia 3	Ethnor
Cosogan	Biocare	Pharol A Exp	Phar East
Coscopin BR	Biological Evans	Phensedyl	Rhone Poulenc
Cheston Exp	Protec (Cipla)	Polaramine	Fulford
Cozy Kid	Ind. Swift Ltd.	Rinostat	SIL Pharma
Comed plus cough	Jenner Medico Lab	Recofast plus	Plethico
Coftrit Cough	Moxy Lab	Recofast plus	Plazma
Corex	Pfizer	Rhizolan	Oriental chemical
Cofexol Cough exp.	Usan	Respirol	Nutri Thera
Deletus D	Nicholas	Siniz	Arochema
Diphenpect	British Pharm	Seumol plus	Blue Shield
Ephedrex	Alembic	Spurex	Health Care
Easex plus	Docman	Syrokof	Indian National Drug
Ephex A	Stadchem	Symix Exp	Kerala State Drug
Ephrilime	Union Drug	Sudarose Cough Linct	Medirose
Euphomin	Juggat	Silentol	Shanti Pharma
Fenidron	Continental	Solvex exp	Somatico
Glucorex cough	Gluconate India	Siricodin	South Indian Research
Glycofex	Glyco	Stebon exp	Stephan
Hystalin cough	Mejda Mark	Sunsedatone	Sunways
Hyposedin	Eisen	Soothex cough	Win Medicare
Isofed	Macleods	Toslin	Tosc
Ipharex cough	National Chem & Pharm	Tossex Improved	Sarabhai
Kofhist cough	Heiko	Tussex	Nutri Thera
Kofron	Agron	Tussacron cephedrine	Acron
Kofit	Bronkol	Tusq	Blue Cross
Lifedryl exp	New Life Pharma	Vasomin Exp	Lancet
		Vasophrex	Biogenics

Zadine DM	Fulford
Zadine Maxi	Fulford

37. FIXED DOSE COMBINATION OF LAXATIVES AND/OR ANTI-SPASMODIC DRUGS IN ENZYME PREPARATIONS.

REASON FOR BANNING : Laxatives/ antispasmodic with enzymes Enzyme preparations are normally given for dyspepsia and addition of laxatives and/or antispasmodics are likely to be habit forming.

Brand	Manufacturer
Molzyme	FDC

38. FIXED DOSE COMBINATION OF METOCLOPRAMIDE WITH OTHER DRUGS EXCEPT FOR PREPARATIONS CONTAINING METOCLOPRAMIDE AND ASPIRIN/PARACETAMOL.

REASON FOR BANNING : Metoclopramide is primarily indicated for nausea and vomiting, particularly in gastro-intestinal disorders and treatment with cytotoxics or radiotherapy.

In migraine, because headache is associated with vomiting, a FDC of metoclopramide with paracetamol may be permissible. Besides, it increases absorptions of aspirin and paracetamol. It adversely interacts with other drugs-antagonism of effect of antimuscarinics on gastro-intestinal activity, increases risk of extrapyramidal effects with antipsychotics.

Brand	Manufacturer
Maxeron-MPS	Wallace
Propamid	CFL Pharma

39. FIXED DOSE COMBINATION OF CENTRALLY ACTING ANTI-TUSSIVE WITH ANTIHISTAMINE HAVING HIGH ATROPINE LIKE ACTIVITY IN EXPECTORANTS.

REASON FOR BANNING : According to BNF there is no evidence that any drug can specifically facilitate expectoration. For this reason, expectorant cough medicines have been described as “an expensive myth”. Therefore there is no rationale for their use.

The drawbacks of prescribing cough suppressants are rarely outweighed by the benefits of treatment and only occasionally are they useful, as for example, if sleep is disturbed by a dry cough. Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis. Though commonly used in acute bronchitis and pneumonia, they can be harmful; such conditions are best treated by prompt administration of antibacterial drugs. Cough suppressants such as codeine, dextromethorpan and pholcodine are seldom sufficiently potent to be effective and all tend to cause constipation. The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children and should be avoided altogether in those under one year of age.

Compound cough preparations have no place in the treatment of respiratory disorders,

and such preparations are to be deprecated not only as irrational but also for leading to patients receiving inappropriate drugs.

See also 36 and 40, P.53 and 56

Brand	Manufacturer
Corex	Pfizer
Cosome	Merck
Deletus	Nicholas
Dristan expectorant	Wyeth
Exiplon	Khandelwal
Grilinctus	Franco Indian
Mintus cough Linctus	Uniloids
Phensedyl cough linctus	Rhone Poulenc
Protussa plus	Boots
Tossex improved	Sarabhai
Tuxyne	Franco Indian

40. PREPARATIONS CLAIMING TO COMBAT COUGH ASSOCIATED WITH ASTHMA CONTAINING CENTRALLY ACTING ANTI-TUSSIVE AND/OR ANTIHISTAMINE.

See also 36 & 39, P. 53 and 55

REASON FOR BANNING : According to BNF there is no evidence that any drug can specifically facilitate expectoration. For this reason, expectorant cough medicines have been described as "an expensive myth". Therefore there is no rationale for their use.

The drawbacks of prescribing cough suppressants are rarely outweighed by the benefits of treatment and only occasionally are they useful, as for example, if sleep is disturbed

by a dry cough. Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis. Though commonly used in acute bronchitis and pneumonia, they can be harmful; such conditions are best treated by prompt administration of antibacterial drugs. Cough suppressants such as codeine, dextromethorphan and pholcodine are seldom sufficiently potent to be effective and all tend to cause constipation. The use of cough suppressants containing codeine or similar opioid analgesics is not generally recommended in children and should be avoided altogether in those under one year of age.

Compound cough preparations have no place in the treatment of respiratory disorders, and such preparations are to be deprecated not only as irrational but also for leading to patients receiving inappropriate drugs.

41. LIQUID ORAL TONIC PREPARATIONS CONTAINING GLYCER/OPHOSPHATES AND/OR OTHER PHOSPHATES AND/OR CENTRAL NERVOUS SYSEM STIMULANT AND SUCH PREPARATIONS CONTAINING ALCOHOL MORE THAN 20 PER CENT.

REASON FOR BANNING : The glycerophosphates were introduced into medicine on the grounds that lecithin contains phosphorus in the form of glycerophate radical and that these compounds would be more easily assimilated by the tissues, particularly by the brain. There is no evidence to support this assumption.

Brand	Manufacturer
Alton	Albert David
Calron	East India
Mynberrys	Juggat
Orheptal	Merck

42. FIXED DOSE COMBINATION CONTAINING PECTIN AND/OR KAOLIN WITH ANY DRUG WHICH IS SYSTEMATICALLY ABSORBED FROM G 1 TRACT EXCEPT FOR COMBINATIONS OF PECTING AND/OR KAOLIN WITH DRUGS NOT SYSTEMATICALLY ABSORBED.

REASON FOR BANNING : Absorbants such as kaolin and Pectin are not recommended for acute diarrhoeas. The first line of treatment in acute diarrhoea, as in gastroenteritis is prevention or treatment of fluid and electrolyte depletion. The absorbent properties of Kaolin and pectin may influence the gastro-intestinal absorption of other drugs and hence its combination with other soluble drugs is not advisable.

Brand	Manufacturer
Acidin	East India
Bestogy 1 F	Usan
Chlorabin	AFD
Deemet	Lark
Dipack	Frio
Dazol	Kerala State Drug
Diarrest	Contour
Entinol	Popularchem
Entrozyme	Stadmed

Furatos	Tose
Furadone	Roland
Farnid F	Phar East
Furamin	Rays Labs
Genolyte-N	Geno
Nitrolin	BH Chemical work
Neldar	Phar East
Neldar F	Phar East
Neokal	Sunways
Peckasy1 F	Aeron
Unizole-H	Unicure

43. CHLORAL HYDRATE AS A DRUG

REASON FOR BANNING : Chloral hydrate is corrosive to skin and mucous membranes unless well diluted and may cause gastritis with nausea and vomiting. Allergic skin reactions very occasionally occur from several hours to 10 days after a dose. Better sedative and hypnotics are available.

44. TOOTH PASTES/TOOTH POWDERS CONTAINING TOBACCO (COSMETICS)

REASON FOR BANNING : Is habit forming and the paste and powders applied to teeth are likely to be kept in mouth for longer periods causing irritation and likelihood of mouth cancers.

45. DOVERS POWDER/DOVERS POWDER TABLET

REASON FOR BANNING : Dover's powder contains opium that is habit forming. It is likely to paralyse intestines in children

resulting in absorption of toxins and worsening the child's condition.

46. ANTIDIARRHOEAL FORMULATION CONTAINING KAOLIN, PECTIN OR ATTAPULGITE OR ACTIVATED CHARCOAL.

REASON FOR BANNING : Absorbants such as kaolin and Pectin are not recommended for acute diarrhoeas. The first line of treatment in acute diarrhoea, as in gastroenteritis is prevention or treatment of fluid and electrolyte depletion. The absorbant properties of Kaolin and pectin may influence the gastro-intestinal absorption of other drugs and hence its combination with other soluble drugs is not advisable.

Brand	Manufacturer
Streptomagna	Wyeth

The wording is defective as it means all Kaolin or pectin containing combinations are banned. But in item No. 42 it says Kaolin & pectin with absorbable antidiarrhoeals is allowed.

47. ANTIDIARRHOEAL FORMULATION CONTAINING PHTHALYL SULPHATHIOZOLE, OR SULPHAGUANIDINE OR SUCCINYL SULPHATHIOZOLE.

REASON FOR BANNING : Insoluble sulphas: The value of insoluble sulphas in the treatment and prevention of intestinal infection is limited by the increasing resistance of enteric bacteria. Prolonged use may lead to overgrowth

of candid spp.

The first line of treatment in acute diarrhoea, as in gastroenteritis, is prevention or treatment of fluids and electrolyte imbalance. In bacillary dysentery the use of appropriate antibiotic be preferred.

Brand	Manufacturer
Aldiamycin	Alkem
Enteroguanidine	Albert David
Saril	Rallis
Thalazole	Rhone-Poulenc

48. ANTIDIARRHOEAL FORMULATION CONTAINING NEOMYCIN OR STREPTOMYCIN OR DIHYDROSTREPTOMYCIN INCLUDING THEIR RESPECTIVE SALTS AND ESTERS.

REASON FOR BANNING : Streptomycin is mainly used in the treatment of tuberculosis Streptomycin is rarely used in the treatment of non-tuberculosis infections due to organisms sensitive to other antibiotics. The oral use of streptomycin for treatment of intestinal infections has been dropped in Martindale 3rd edn. 1993.

Many strains of bacteria initially sensitive to streptomycin become resistant during therapy and this resistance may develop very rapidly. Resistance to streptomycin in non tuberculous infections may develop within two or three days of instituting treatment, whereas in tuberculosis the slower rate of multiplication of the infecting organism may delay development of complete resistance for 6 weeks or more.

There is complete cross-resistance between streptomycin and dihydrostreptomycin, and partial cross-resistance between streptomycin, neomycin, kanamycin, and paronomycin.^{48.1}

Brand	Manufacturer
Aldiamycin	Alkem
Ambizyme forte	Emcee lab
Diarest	Centaur
Genolyte N	Geno
Inseptin	IDPL
Imosec S	Ethnor
Kaltin c Neomycin	Abbott
Klassak	Plethico
Neldar	Phar East
Neokal	Sunways (Ind)
Renokab	John Wyeth
Saril	Rallis Tab
Streptomagna	John Wyeth
Streptomagna gel	John Wyeth
Sulfamycin	Nutri Thera
Streptotriad	Rhone Poulenc Tab
Solstrep	Unicure Capsule

49. LIQUID ORAL ANTIDIARRHOEALS OR ANY OTHER DOSAGE FORM FOR PAEDIATRIC USE CONTAINING DIPHENOXYLATE OR LOPERAMIDE OR ATROPINE, OR BELLADONA INCLUDING THEIR SALTS OR ESTERS OR METABOLITES, HYOSCYMINE

OR THEIR EXTRACTS OR THEIR ALKALOIDS.

REASON FOR BANNING : The presence of subclinical doses of atropine sulphate in preparations containing diphenoxylate may give rise to the side effects of atropine in susceptible individuals or in overdosage. The intestinal paralysing effect of diphenoxylate and loperamide particularly in infants and children is likely to result in absorption of the intestinal toxins (bacterial) leading to death.^{49.1} These products delay the elimination from the body of the organisms that cause the diarrhoea, and may prolong illness.^{49.2}

Death due to Respiratory distress resulting from paralysis of diaphragm and the respiratory muscles is known to occur in children due to accidental overdose of gut paralyzers.^{49.3}

Brand	Manufacturer
Diarlop oral	Jagson pal
Diarlop Plus	Jagson Pal
Disny Plus	Pharmindia
Dystop	Jeps
Klassak	Plethico
Loper	Centaur
Loperil	Acron
Motionil	Lancet Remedies
Motionil F	Lancet Remedies
Neostep	Swastic
Pelopem	Mercury
Ridol	Gufic
Vegyl L	Velco

48.1. Martindale 27th edition, 1977 pg. 1183

49.1. Taste of Tears, VHAI, 1984

49.2. Rational Use of anti-diarrhoeals, UNICEF, WHO

49.3. Taste of Tears, VHAI, 1984

50. LIQUID ORAL ANTI-DIARRHOEALS ANY OTHER DOSAGE FORM FOR PAEDIATRIC USE CONTAIN HALOGENATED HYDROXY QUINOLINES.

See No. 13, P. 41

CLIOQUINOL/HYDROXYQUINOLINE/
QUINIOCHLOR/CHINOFORM/
CHLORPOPDIOQUIN/VIOFORMO/
CLIOCHINOLUM/
IDOCHLOROHYDROXYQUIN/
IDOCHLOROHYDROXYQUINOLINE/
DI-IDOHYDROXYQUINOLIN

CLIOQUINOLS (Hydroxyquinolines)

Brand	Manufacturer
Lumigyl	Plazma
Novanidagyl	P & B
Stadmed	Stadmed

REASON FOR BANNING : Dangerous. Causes SMON, a painful nerve disease which causes limb paralysis, blindness and lack of bladder control. Effective and safer anti-amoebic drugs are available.

“Clioquinol has caused thousands of cases of SMON in Japan and elsewhere. A condition involving continuous pain, paralysis, blindness and, in extreme cases, death.

“There is no convincing evidence to suggest that....clioquinol (is) effective in the prophylaxis of travellers' diarrhoea.

“Hydroxyquinolines are active only on organisms present within the intestinal lumen.

Used alone, therefore, they are active only in the absence of significant tissue invasion - a development that cannot be excluded with certainty even in patterns with asymptomatic amoebiasis.”

Diodohydroxyquin and iodochloro-hydroxyquin have widely and all too often been indiscriminately employed for the treatment of diarrhoea. The use of these drugs, particularly at high doses for prolonged periods is unfortunately associated with significant risk. Administration of diodohydroxyquin in high doses to children with chronic diarrhoea, for example, has been associated with optic atrophy, permanent loss of vision.

Broxyquinoline has exactly the same properties concerning toxicities and there are cases in Sweden with exactly the same clinical picture as the clioquinol cases. So there is nothing to say that there are any differences in the toxicity of the different halogenated oxyquinolines.

Antimicrobial drugs are not indicated for the routine treatment of acute diarrhoea., Their indiscriminate use must be discouraged not only because they are often of no value, but they are needlessly expensive and can also be harmful.¹

It was suggested that the Japanese epidemic might be due to genetic susceptibility but a few similar cases of SMON have been reported from several other countries in association with clioquinol or related hydroxyquinoline derivatives, such as broxyquinoline or di-iodohydroxyquinoline. Oral preparations of clioquinol have now been banned in most countries.

USED: For diarrhoea and amoebic

dysentery.

REASON FOR BANNING : All the hydroxyquinolines carry a high risk of adverse effects and most experts agree that their use should be avoided because they are ineffective and dangerous. Majority of the infant and childhood diarrhoea is due of viral origin and hydroxyquinoline plays no advantage in treatment of such diarrhoeas.

Brand	Manufacturer
Diodoquin	Searle
Dysentol-N	Bronkol
ENTROZYME	Stadmed

COUNTRIES WHERE BANNED OR SEVERLY RESTRICTED

1970	Japan
1974	Norway
1975	Sweden
1976	German Democratic Republic
1978	Denmark, Bangladesh, Philippines
1983	Italy, Nepal, Dominican Republic, Zimbabwe, Zambia.
1985	Honduras, Switzerland, Cuba. Federal Republic of Germany, Spain, France, Netherlands, Saudi Arabia and Venezuela. India's neighbouring countries, Nepal, Bangladesh, Sri Lanka and Malaysia have banned this drug. Parke Davis who consider themselves pioneers in sales of this combination for diarrhoea have, in view of the increasing medical evidence against its use, voluntarily withdrawn their products, mexasform and enterovioform from the world market.

SAFER ALTERNATIVES: For diarrhoea: oral rehydration therapy. For amoebic dysentery: oral rehydration therapy and metronidazole.

51. FIXED DOSE COMBINATIONS OF ANTIDIARRHOEALS WITH ELECTROLYTES

REASON FOR BANNING : WHO has no doubt about the role of antidiarrhoeal products. "There are no drugs available at present that will safely and effectively stop diarrhoea. Most medicines for diarrhoea are either useless or harmful". ORT is effective in preventing and treating almost all cases of dehydration from acute watery (non bloody) diarrhoea, including cholera. As such there is no advantage in combining on antidiarrhoeal with electrolyte solution besides, some of the antidiarrhoeals are likely to adsorb the electrolytes.

Brand	Manufacturer
Furatos	Tosc
Genolyte N	Geno
Neldar	Phar East
Neldar F	Phar East
Neokal	Sunways

52. PATENT AND PROPRIETARY ORAL REHYDRATION SALTS OTHER THAN THOSE CONFORMING TO THE FOLLOWING PARAMETERS :

REASON FOR BANNING : Home made Oral rehydration solutions lower in sodium (35-60 mmol/litre) and higher in glucose (up to 200

mmol/litre) than the WHO formulation may be of benefit for mild to moderate diarrhoea, when the body's homoeostatic mechanisms are still working and will not be harmful, but they may be suboptimal in correction of fluid loss and electrolyte imbalance. In the more severe diarrhoeas the WHO formulation is more effective in correcting dehydration, it carries no danger of hypernatraemia if used correctly.

Sugar is required for the absorption of electrolytes but high concentrations of glucose can cause osmotic diarrhoea & exacerbate existing diarrhoea. This can occur when the sugar content in the ORS is high as in some commercial ORS packets or if mixing is improper i.e. use of more powder less water. Since the ORS packet sizes differ so much.^{52.1}

Improper mixing of ORS packet can result in more salt intake and can cause hypernatremia which presents as irritability, mental confusion, convulsions, twitching, irregular respiration, stupor and eventually coma.^{52.2}

(a) Patent and Proprietary oral Rehydration Salts on reconstitution to one litre shall contain :—

Sodium—50 to 90 millimoles

Total osmolarity—240 to 290 millimoles

Dextrose : Sodium molar ratio—Not less than 1 : 1 and not more than 3 : 1.

(b) Patent and Proprietary cereal based Oral Rehydration Salts on reconstitution to one litre shall contain :—

Sodium—50 to 90 millimoles.

Total osmolarity—Not more than 290 milli osmoles.

Precooked rice—Equivalent to not less than 50 gms and not more than 80 gms as total replacement of Dextrose.

WHO/UNICEF formula of ORS ORS Bicarbonate

Ingredient	Quantity
Sodium chloride	3.5 gm
Sodium bicarbonate	2.5 gm
Potassium chloride	1.5 gm
Glucose (dextrose)	20.0 gm
Potable Water	1 litre

ORS Citrate

Ingredient	Quantity
Sodium chloride	3.5 gm
Trisodium citrate dihydrate	2.9 gm
Potassium chloride	1.5 gm
Glucose	20.0 gm
Potable Water	1 litre

Over Rs. 220 million worth of commercial ORS formulations were sold in 1993.

(c) Patent and Proprietary Oral Rehydration Salts (ORS) may contain aminoacids in addition to Oral Rehydration Salt conforming to the parameters specified above and labelled with the indication for "Adult Cholorrhic Diarrhoea only".

(d) Patent and Proprietary Oral Rehydration Salts shall not contain mono or

52.1. Taste of Tears, VHAI, July 1984, P. 28

52.2. Taste of Tears, VHAI, July 1984, P. 29

ORS ELECTROLYTES

Name of Product	Manufacturer	Packaging in gms	Price per packet in Rupees	Price per 10 gms. Rupees
Dextrolyte	Tablets	35.09	10.95	3.13
Electral	FDC	7.09	2.95	4.21
		35.09	10.15	2.90
Electrobion	Merck	28.59	8.64	3.03
Emlyte	M.M. Labs	40.09	9.30	2.33
Leclyte	Albert Davis	30.0	7.99	2.66
Ledyte-W	Albert Davis	27.5	6.84	2.49
Peditral	Searle	6.69	2.0	3.03
		33.09	9.65	2.92
Peditral-90	Searle	5×5.89	9.42	3.20
Prolyte	Cipta	27.5	5.91	2.15
Punarjal	FDC	6.0	2.60	4.33
Relyte	Rallis	5×5.68	12.95	4.56
Ricetral	FDC	11.8	3.37	3.18
		59.0	13.30	2.25

*Ref Problem Packets Commercial ORS Packets some Bitter facts Dr. Mira Shiva, Dr. Unnikrishnan, VHAI

polysaccharides or saccharin sweetening agents.

The constituents of ORS packets should be the one in the WHO's essential drugs list. ORS packets are available in the market not following the prescribed ORS constituents should be banned because of the following reasons:

1. The glucose concentration is more than 20 gm per litre as such solutions can cause osmotic diuresis and more dehydration.
2. Flavour and colour may be harmful as it may cause respiratory allergy.
3. Undesirable constituents viz. minerals etc.

are added which are not required and thus are useless and irrational.

4. The ORS packets should be standardized and have a uniform dose packing.

Examples of Irrational Electrolyte Salts

S.No. Brand-Producer (Contents)

1. Electral sachet 51.5 g.-Fair Deal (Cal. Lactate 1.1973%, Pot. Chlor., 3.6165%, Magn. Sulph. 0.9573%, Sod. chl. 0.5675%, Sod. Acid Phos., Dextrose q.s.)
2. Electral Forte sachet 30 g.-Fair Deal (Sod. Chl. 3.5g., sod.cit.2.9g., pot.chl.1.5g., dextrose 20g.)

3. Electral-M sachet 50 g. granules—Fair Deal (Sod.chl.0.78%, Pot.chl.4.96%, Sod.bicarb.3.13%, Dried Sod.Phos 0.76%, Sod.Cit.(anhydrous)6.65% Dried Mgn Sulp. 1.036%, calloetate 1.64%, Dextrose q.s., permitted colour tartrazine 0.004%.)

4. Emlyte sachet 35 g & 70 g.—M.M.Labs (Sod. Chl. 3.5 g., Sod.bicarb2.5 g., pot.chl.1.5 g., glucose 20 g. per 35 g.)

5. Emlyte-S sachet 35 g.—M.M. Labs (Sod.Chl. 3.5 g., Sod.bicarb.2.5 g., pot.chl. 1.5 g., sporlac 250*10, glucose 20 g. per 35 g.)

6. Leclyte sachet 80—Albert David (Cal. Lact. 0.545%, Pot. Chl. 2.337%, Mag. Sulph.0.736%, Sod.Chl. 0.365%, Sod, acid phos. 0.975%, sod.cit. 1.839%, dextrose q.s.)

7. Peditral 40 g.—Searle (Sod. chl. 4.3875%, pot.chl. 3.73%, sod.bicarb.4.2%, dextrose 86.0825%.)

SAFER ALTERNATIVES : Early and adequate intake of home based fluids (rice water, kanji water, sugar-salt solution, shikanji (lime juice with sugar and salt) herbal tea, saunf or ajwain water, jeera water, lassi, salted butter milk, tender coconut water, dilute dal water).

The bottom line of course is that safe drinking water should be made available to the people and this is the primary prevention against diarrhoea and dehydration. Methods of decontamination of water at home level must be made known and available e.g. boiling, putting water in transparent containers in the hot sun, use of chlorine, iodine drops.

53. FIXED DOSE COMBINATIONS OF PHENYLBUTAZONE OR OXYPHEN BUTAZONE WITH ANY OTHER DRUG

Oxyphenbutazone Combinations

Brand	Company
Alcapyrine	Usan
Algiril	P & B Pharms
Brugesic	Brawn
Butagin	Tablets Ind.
Butacortindon	Indon
Butadex	Cadila
Butamol	Associated Pharma
Butamol	Angel
Butanal	Roland Pharma
Butalgin	Associated Pharma
Butaproxyvon	Wockhardt
Flamar	Indoco
Flamar P	Indoco
Flamon	Paans
Flamox Forte	Glenmark
Glycozide	Glyco
Inflar	Navil
Inflaryl AD	Geno
Inflazone	Contaur
Jagril	Jagson Pal
Maxigesic	Plethico
Methrazone	Unicure
Oxin	Synokem
Oxynal	Euphoric
Oxypamol	Shalaks
Oxypamol Forte	Shalaks
Ploxy	Beckcem
Prestigesic	Synthico
Poal	Phar East
Reducin A	Unique
Remezide	Glyco

Rumin	INDC
Somagesic	Somatico
Somagesic Forte	Somatico
Systaflam	Systopic
Tromalgin	La Pharma
Tudol	Syntho

Phenylbutazone combinations

Brand	Manufacturer
Actimol	Pharmed
Aigesin	Alembic
Arcure	Nu Life
Butarin	Themis
Decapyrin-M	Swastik
Dexapyrin-D	Sarvodaya
Esgipyrin	S.G. Pharma
Kebutacine	Kee Pharma
Dicipyrene-N	DCI
Parazolandin	SG Pharma
Phenorin	Jagson Pal
Udipyrine	UDH
Zolandin Alka	S G Pharma

REASON FOR BANNING: Can cause agranulocytosis^{53.1} (a fatal blood disease), stomach ulcers, liver and kidney damage.

"...because of its toxicity (Phenylbutazone) is not employed as a general analgesic or antipyretic".^{53.2}

"Phenylbutazone should be employed only after other drugs have failed, and then only after careful consideration of the risk involved as

compared with the advantage to the patient."^{53.3}

"Side-effects occur in 20-40 per cent of patients."^{53.4}

Production and sale of Tanderil-Phenylbutazone-has been withdrawn from the world market by Ciba-Geigy.^{53.5}

Oxyphenbutazone has been used by mouth in rheumatic disorders such as ankylosing spondylitis, Osteoarthritis, rheumatoid arthritis but such use is no longer considered justified owing to the risk of severe haematological adverse effects.^{53.6}

USED: Mainly for inflammation, but also for pain and fever.

EXAMPLE OF COMBINATIONS:
Esgipyrin tablets (S.G. Pharma) :
Phenylbutazone, propyphenazone.

COUNTRIES WHERE BANNED:

- | | |
|------|---|
| 1984 | United Arab Emirates, Cyprus, Finland, Iceland, Tunisia, Jordan, Barbados, Zimbabwe, Spain, Bangladesh. |
| 1985 | Netherlands, Sweden, New Zealand, Oman, Turkey, Austria, Chile, Congo, Federal Republic of Germany, United Kingdom, Hungary, Israel, Japan, German Democratic Republic, Italy and Philippines have banned |

53.1 Agranulocytosis is a blood disease (often fatal) in which the bone marrow fails to produce white blood cells (which fight infection and are essential to life) so that patient easily succumbs to infection and can die

53.2 Martindale, The Extra Pharmacopoeia, 30th edition 1993, P. 29

53.3 Goodman & Gilman, The Pharmacological Basis of Therapeutics 8th edition, 1991, P. 655

53.4 British National Formulary, 1983, P. 299 Quoted.

53.5 Ciba-Geigy : Press Release, April 1985

53.6 Martindale, The Extra Pharmacopoea : 30th edition, 1993, P. 27

phenylbutazone but not oxyphenbutazone whereas Finland has not banned phenylbutazone.

Note:—The Health Ministry of the Government of India has given a directive that oxyphenbutazone and phenylbutazone be used only in acute ankylosing spondylitis and acute gouty arthritis.

SAFER ALTERNATIVES: For inflammation : aspirin or indomethacin, for pain, fever : aspirin or paracetamol.

54. FIXED DOSE COMBINATION OF ANALGIN WITH ANY OTHER DRUG OTHER THAN ANTI-SPASMODICS.

Analgin Containing Drugs:—

Brand	Manufacturer
Apigin	Associated Pharma
Anmol	Medirose
Anzepam	Lister Labs
Anacet	Semit
Avafortan	Khandelwal
Butalgin	Associated Pharma
Butagin	Tablets India
Basemol	East African
Biogin	Biomed
Butaron	Agron
Butacortindon	Indon
Capagin	Kon Test
Corogesic	Osho Pharma
Dicipyrin-N	DCT Pharma
Dolored	Redson

Doloenx
Doloson-A
Dublactin
Doloxyl
Diapar
Dualgin
Dologin
Doloril A
Epigesic
Esgipyrin-N
Eucrasil
Fargesic
Ginoxal
Inflar
Inflaryl
Maxigesic
Metragin
Molgin
Metoxyl
Neopyrin
Nycin
Nopirex
Newtril
Oxyzol
Oxalgin
Osygin
Oxin
Oxynal
Oxygin
Oxyzone
Oxymole
Oxogin
Oxan
Patalgin Plus
Pamolgin - C
Patalgin

Swastik Formulation
Redson
Tablets India
Pharmindia
Navil Labs
Pharm Products
Uni Drugs India
Indica Labs
Eros Pharma
S.S. Pharma
Eisen Pharma
Phar East
Wings Pharma
Navil Labs
Geno
Plethico
Me lico labs
Gracure
Acron
Indus Pharma
Nymph
Medico Labs
Trio Remedie
Medirose
Cadila
Pharmasynth
Axar
Euphoric Pharma
Hima Research
Belco Pharm
Beo-Med
Zeal
Medico
Acron
Paam Pharma
Acron

Paralginol	Veco
Paralgin C	Emcee
PFI	Medi Products
Paral 530	Pharmindia
Painil	Lancet Remedies
Phenolgin	Paam
Pyralgin	Wellcross India
PAC	Wings Pharma
Rexidic	Biocare
Serpain	Shanti Pharma
Tudol	Syntho
Timol	T.M. Thakore
Tosgin	Tosc
Ultragin	Belco Pharma
Ultragin	Wyeth
Zinol	Redson
Zimalgin	Rallis

There are many generic brands of analgin available in the form of tablets, injectible, and syrup. Most of the analgin combinations now banned, will continue to use the same brand name by changing the formulation.

Due to the wording after ban following are the single ingredient (analgin) brand products which continue to be marketed.

A. Single Ingredient Analgin

Brand	Manufacturer
Benalgis	Franco Indian
Cemizol	IDPL
D-pyrone	British Pharma
Indalgin	Indus Pharma
Novalgin	Hoechst
Stargin	Star Pharma

B. Following are the combinations of anti-spasmodics with analgin.

Brand	Manufacturer
Baralgan	Hoechst
Colipam	Litaka Pharma
Colocspasm	Leben Labs
Fenalgin	Associated Pharma
Kidgan Oral	Lancet Remedies
Maxigan	Unichem
Medalgan	Medico Labs
Metalgan	Modern Labs
Multispas	Healthcare Pharma
Neurospas	Ind Swift
Relispas	Tribhuvan Pharma
Religan	Acron
Spasmowin	Belco Pharma
Spasgan	La Grande
Sparid	Jeps Pharma
Spasmizol-K	IDPL
Spasmogan	Semit
Spasmaton	Tuton Pharma
Spasmalgin	Veco
Spasgun	Wings Pharma
Spalgin	Epcee Formulations
Trispas	Tosc
Vespanil	Veco

While “analgin combinations” have been banned the antispasmodic analgin combinations and plain analgin is allowed.

Note:– If the analgin combinations are to be banned because of the hazards associated with analgin - the sale of analgin as a single ingredient drug or its combination with anti spasmodics should not be allowed. –Ed.

REASONS FOR BANNING: Dipyron³e, like Amidopyrine can cause agranulocytosis - a fatal blood disease. Safer, cheaper adequate substitutes are available.

“Administration of dipyron is associated with an increased risk of agranulotosis and with shock.”

55. FIXED DOSE COMBINATION OF DEXTROPROPOXYPHENE WITH ANY OTHER DRUG OTHER THAN ANTI SPASMODICS AND/OR NSAIDS

Brand	Manufacturer
Butaproxyvan	Wockhardt
Corbutyl	Roussel
Dexovon	U.S. Vitamins
Dolopar Plus	Micro
Parvon	Jagsson Pal
Proxylab	Wockhardt
Proxylon	Wockhardt
Sudhinol	Ranbaxy
Systaflam	Systopic
Walagesic	Wallace
Wygesic	Wyeth
Darvocat	Elillily Ranbaxy

There are a disturbing number of fatalities from either accidental or intentional overdose with dextropropoxyphene. Many reports emphasise the rapidity with which it ensues. Death within an hour of overdose is considered by some not to be uncommon. Overdose is often complicated by patients also taking alcohol and using mixed

preparations such as dextropropoxyphene with paracetamol or aspirin.

“Prolonged use of dextropropoxyphene hydrochloride may lead to dependence of the morphine type. It has been subject to abuse”^{55.1}

Given alone dextropropoxyphene is a very weak analgesic, and an important disadvantage when given with aspirin or paracetamol is that overdose (which may be combined with alcohol) is complicated by respiratory depression and acute heart failure due to the dextropropoxyphene and by hepatotoxicity due to paracetamol.

Dextropropoxyphene is not mentioned in PDR 2.

56. FIXED DOSE COMBINATION OF A DRUG, STANDARDS OF WHICH ARE PRESCRIBED IN THE SECOND SCHEDULE TO THE SAID ACT WITH AN AYURVEDIC, SIDDHA OR UNANI DRUG.

The fixed dose combination of a drug, standards of which are prescribed in second schedule to the said act – are not known to general public nor is the list of brand names affected by the above ban available at present. We hope that the Drug Controller of India will make the list of banned drugs available to the public in keeping with the direction of the Supreme Court.

55.1. Martinade : The Extra Pharmacopoea : 30th edn. 1993 P. 1071

DRUGS WHICH SHOULD BE BANNED OR SEVERELY RESTRICTED

Countries which have never allowed these drugs, and therefore do not need to ban them are not listed here. Other countries (also not listed) have a legal structure which discourages the introduction of hazardous or irrational drugs.

1. ANABOLIC STEROIDS FOR CHILDREN

REASONS FOR BANNING: Dangerous. Stunts growth in children (prematurely stops long bones growing) and disturbs their sexual development (e.g. irreversible masculinisation of girls).

Their use as body-builders or tonics is quite unjustified.”¹

Large and repeated doses in early puberty may cause closure of the epiphyses and stop linear growth. Children may experience symptoms of virilization.²

“Serious disturbances of growth and of sexual and osseous development can occur when androgens are given to children”.³

“Under the provisions of the Drugs (Control) Ordinance, low strength preparations were banned following unacceptable promotion encouraging their use in children suffering from malnutrition. The action in Bangladesh was taken having regard to inadmissible

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1. B.N.F. 1983. P. 237
 2. Martindale 30th edn. 1993 P. 1166
 3. Goodman & Gilman. 8th edn. 1991 p. 1420
-

promotion of products containing anabolic steroids for malnourished children. These substances remain available at higher dosage in many countries, including Bangladesh, for several highly specific but limited indications that apply to selected patients with chronic debilitating and emaciating diseases, particularly associated with neoplasia and some types of aplastic anaemia.”

USED: As a tonic and growth stimulant for children (unjustifiably), and as supportive treatment for rare diseases such as aplastic anaemia and old age osteoporosis.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED :

BANGLADESH

SAFER ALTERNATIVE: Nutritious food to maintain normal growth. Testosterone is used for aplastic anaemia and old age osteoporosis in men. Oestrogen is as effective as anabolic steroids for osteoporosis in women.

No brands available in the market.

See also No. 26, P. 38

2. FIXED DOSE COMBINATIONS OF CODEINE/ DEXTROMETHOR-PHAN/ NOSCAPINE/ LEVOPROPOXYPHENE WITH EPHEDRINE AND/OR ANTIHISTAMINICS,

FOR THE TREATMENT OF DRY COUGH.

Codeine, dextromethorphan, noscapine and levopropoxyphene are habit forming substances.

Codeine, dextromethorphan and noscapine are derivatives of opium.

Codeine is a cough suppressant.

Ephedrine is a bronchodilator, it stimulates the respiratory centre, causes shrinking of mucous membrane, anxiety, restlessness, insomnia and can precipitate urinary retention in patients who have prostatic hypertrophy.

“Cough Suppressants are used to suppress irritant unproductive coughs but few have been shown to be effective by controlled clinical studies. The ideal cough suppressant should diminish the frequency and distress of coughing whilst not impairing reflex mechanisms allowing clearance of secretions. Their (dextromethorphan, noscapine, codeine, diamorphine, etc.) use in conditions characterised by the production of bronchial secretions, such as chronic bronchitis, or cystic fibrosis may result in sputum retention and the development of pneumonia”.¹

Ephedrine may increase the side effects of theophylline (gastrointestinal upset, insomnia, irritability and other CNS stimulant effects) without enhancing its efficacy. Probably it is best to avoid this combination.

1. Martindale : The Extra Pharmacopoeia : 30th edn. 1993 P. 741

COUGH EXPECTORANT

SIDE EFFECTS: Occasionally causes drowsiness, dizziness, excitation, mental confusion, gastrointestinal disturbances. Very high doses may produce respiratory depression.

PRECAUTIONS: Dextromethorphan should be administered with caution to patients with liver disease and to asthmatic patients.

Brand	Manufacturer
Alex Cough Formula	Lyka
Clistin	Ethnor
Clistin-DMR	Ethnor
Cosome	Merck
Deletus	Nicholas
Eltuss	Elder
Grilinctus	Franco Indian
Histrakof	Kopran
Lastuss LA	FDC
Pedia 3	Ethnor
Protussa Plus	Boots
Respren	Ethnor
Triominic	Wander
Triatussic	Wander
Tusq-P	Bluecross
Zedex	Wockhardt

LEVOPROPOXYPHENE

(1 Benzyl - 3 dimethylamino - 2 methyl - 1 phenylpropyl propionate naphthalene - 2-sulphonate monohydrate cough suppressant).

There are no Levopropoxyphene products in

THE BOSTON STUDY

To prevent a worldwide ban of dipyrene, Hoechst started the so called 'Boston Study' (IAAS, International Agranulocytosis Aplastic Anaemia Study).

The study was published in JAMA in October, 1986.

Based on the result of the Boston Study, Hoechst started making claims of the 'risk estimate' of 1 case of agranulocytosis in every 1,000,000 patients. This has been questioned not only by well-known experts but also by the German Federal Health Office. German Federal Health Office has estimated the risk to be much higher and in its order dated 1.11.86 on dipyrene has said. "The decision of the IAAS does not allow to quantify the absolute risk".

German Drug Controllers explicitly say that "Due to its design Boston Study was not appropriate for supplying data on absolute risks". Boston Study was designed only to study agranulocytosis, but the major side effect of dipyrene is shock and cardiovascular reaction. These reactions are much more often reported than agranulocytosis. The Boston Study did not deal with this risk. The risk of a shock seems to be substantially higher than that of agranulocytosis. Risk of shock was estimated by Prof. Hackenthal (University of Heidelberg) to be of the order of 1 in 50,000 after oral intake and 1 in 5,000 after injection. Less severe hypotension due to shock can be seen even in 1 in 100 patients.

CIMS. No Levopropoxyphene in Pharmaceutical Index and in MIMS.

ANALGIN

"The risk of serious blood disorders in

the presence of availability of safer alternatives do not justify its use".¹

Dipyrone is the sodium sulphonate of Aminopyrine and has similar properties. Its use is justified only in serious or life threatening situations where no alternative antipyretic is available or suitable.

Dipyrone could aggravate haemorrhagic tendencies. Severe hypothermia might result if dipyrone and chlorpromazine were given concomitantly.

Dipyrone is likely to interact with food in the presence of gastric acid which forms potentially carcinogenic N-Nitroso compounds, and particularly nitrous amines.²

The use of this drug and its combination had been banned, withdrawn or severely restricted.

In June 1977, metamizol was withdrawn from the market and prohibited from export by the Food and Drug Administration of USA on the basis of reports of agranulocytosis, a sometimes fatal blood condition, associated with its use. The Director of the Bureau of Drugs found that agranulocytosis cannot be effectively prevented by frequent examination of treated patients since this condition can occur within a few hours following administration of the drug to a sensitive individual. In its decision the FDA cited the availability of effective orally administered drug products such as aspirin and acetaminophen and concluded that the risks

associated with this drug far outweigh any benefit derived from its use, including use in Hodgkin's disease and similar malignant diseases of terminal nature.

The hearing of the German Federal Health Office finally confirmed the assumption of 1981 that one out of 30,000 to 60,000 patients will be affected with agranulocytosis caused by dipyrone. The German Federal Government found that the incidence of agranulocytosis was 24 times as high in users as in non-users. It has severely restricted all other indications excepting rare pain. Besides agranulocytosis and shock, there are other severe adverse reactions like Lyell's Syndrome (scalded skin) and other immune allergic reactions caused by dipyrone.

Another argument of spasmolytic activity of dipyrone injectible is propounded. Upto now there is no scientific proof of any spasmolytic (anti-spasmodic) effect of dipyrone, in therapeutic doses. It is clear that Hoechst does not believe in its own claim of spasmolytic activity, because Hoechst's own antispasmodic combination (Baralgin, Buscopan comp etc.) incorporates separate spasmolytic agents.³

Baralgin made by Hoechst which they recommend for use in Urolithiasis (Kidney Stone). Biliary disorders, Dysmenorrhoea (uterine pain during menstruation) contains: Analgin 500 mg. Pitofenone Hcl 5 mg. fempiverinium Bromide 0.1 mg.

Central Pharmaceutical Affairs Council in Japan recommended that because of

1. Problem Drugs – IOUC-1993

2. Metamizol, kommentar Zu Barichten 4 eber lebensbedrohliche, Deutsches Arzteblatt 10-12-87 P. 2408-2411.

3. Buko Pharma Campaign. Hoechst A Cause of illness, The Pharma Business in the third world 1986. p. 19.

pyrazolone's (derivatives: amidopyrine, dipyrrone, mofebutazone, nifenazone, oxyphenbutazone, phenazone, phenylbutazone) propensity to cause frequent skin eruptions (permanent disfiguring lesions including toxic epidermal necrolysis, exfoliative dermatitis, and Stevens Johnson's Syndrome) pyrazolones should no longer be included in proprietary cold medicines or in antipyretic-analgesic preparation available without doctors' prescription.

COUNTRIES WHERE BANNED OR RESTRICTED : Austria, Australia, Belgium, Chile, Denmark, Finland, France, Greece, Egypt, Israel, Italy, Japan, Korea, Mexico, Nepal, Norway, Peru, Philippines, Saudi Arabia, Singapore, Sweden, Turkey, USA, Venezuela, West Germany, Yemen. It is not available in UK.

"Analgin combinations" have been banned by German Drug Control Authorities and following that, by Pakistan. Analgin combinations have been recommended for being weeded out by our own Drug Technical Advisory Committee in 1987.

Analgin does not appear in the most recent reference text books such as Remington's Pharmaceutical Sciences (1986), Goodman and Gilman (1985). Drug, Facts and Comparisons (1985), Drugs Pharmacology Administration. Toxicity Nurses Reference Library (1985), Physicians Desk Reference, US.

Dipyrrone - What are the Alternatives

The "Arznel-Telegramm", a critical information service for physicians and pharmacists in the Federal Republic of Germany, examined possible substitutes for

dipyrrone and found that dipyrrone can be replaced for all indications by better tolerated or more appropriate analgesics.'

Fever

- * Acetyl - salicylic acid (ASA) : 0.5 - 1g.
- * Paracetamol (Acetaminophen): 0.5 - 1g.
- * Ibuprofen 200 mg - 400 mg.

For children under 15 years paracetamol is the drug of first choice. Children with otherwise harmless viral infections may develop Reye's Syndrome (liver necrosis with encephalopathy) after intake of ASA. Drug treatment has to be supported by physical measures such as wet compresses around the lower legs. Studies proving the superiority of dipyrrone in the treatment of fever, are inadequate, so that this widely held notion seems to be unfounded.

Dysmenorrhoea

- * Ibuprofen
- * Naproxen
- * Other non-steroidal anti-inflammatory drugs (NSAIDS)
- * Pentazocin
- * Dextropropoxyphene

Prostaglandin-synthesis-inhibitors such as ibuprofen and naproxen are a logical and effective principle of treatment, because painful abdominal cramps is caused by certain metabolites of the arachidonic and (prostaglandin). Non-steroidal anti-inflammatory agents are, therefore, superior to common analgesics.

Biliary Colic

- * Pethidine
- * Morphine plus isosorbide dinitrate (ISDN)
- * Pentazocin

The combination of morphine parenteral with ISDN is necessary in order to compensate for the spasmogenic effect of morphine to the unstriated muscles of the biliary tract and the intestine. The efficacy of ISDN is better than that of spasmogenics. If necessary, treatment can be continued with morphine oral and ISDN. Instead of morphine, other opiate can be taken.

Renal Colic

*As for biliary colic, additionally diclofenac, 75 mg. intramuscular (i.m.)

In a comparative analysis, diclofenac 75 mg. i.m. proved to be more effective than pethidine 100 mg. i.m. Further studies confirmed this pain-killing effect for biliary colics too.

Post-Operative and Post-traumatic Pain

- * Morphine
- * Buprenorphine
- * Other Opiates

Since at least during the first few days after an operation or trauma, pain is severe and continuous, pain-relieving treatment should be carried out according to the clock (such as morphine every four hours, buprenorphine every six to eight hours. Dosage intervals vary according to the duration of effect of the opiate used. Non-steroidal anti-inflammatory agents or anti-phlogistics are contra-indicated for subsidence and pain-relief due to the risk of renal insufficiency and should not be used before the fifth day post-traumatically and only in case of normal renal function.

Tumour Pain

- * Morphine oral

*** Other opiates**

There are a number of therapeutic regimens, based on the duration of effect of the drug in order to find the necessary analgesic dosage and to apply the drug according to the clock. For the retarded morphine, the duration of effect seems to be eight hours, just like for buprenorphine. The analgesic effect of pentazocine is limited so that a frequent dosage required. When opiates are used permanently they regularly cause spastic constipation which can be treated with laxatives.

Other Severe Pain

*Paracetamol (Acetaminophen 0.5 - 1 g) plus codeine (50 - 100 mg).

When an analgesic such as acetyl-salicylic acid (ASA) or paracetamol alone is not sufficient, the analgesic effect can be increased by an effective dosage of codeine (at least 50 mg.) The effect of duration is - for both substances - five to six hours so that a pain-relieving treatment is possible, by an administration every four hours.

Myocardial infarction: Clinical Management: General measures: pain relief: Rapid and effective analgesia is the main requirement of most patients in the early stages of myocardial infarction. The opiates, morphine, and diamorphine, are most effective for this purpose. When given by slow intravenous injection, either morphine, 10-15 mg, or diamorphine 5 - 10 mg, result in rapid pain relief. The emetic effect of both drugs result in unwanted circulatory stresses but may be lessened by the routine intravenous of cyclizine 50 mg. Among alternative drugs are

pethidine, methadone, and pentazocine. Pentazocine has been a source of some concern because a rise in pulmonary artery pressure following its administration has been observed in several studies. This finding has been associated with an elevation of left ventricular end-diastolic pressure in one study, suggesting a negative inotropic effect on the left ventricle. This has not, however, been a uniform observation and a direct effect on pulmonary arterioles has also been postulated. In any event, pentazocine, although an effective analgesic in doses of 30-60 mg intravenously, is probably best avoided because of its tendency to produce hallucinations..... Some patients require a second or third dose of analgesic during the first 24-48 hours of admission, others are particularly anxious and benefit from sedation with a benzodiazepine, e.g. diazepam 2 - 5 mg thrice daily... When potent analgesics may not be available; a period of prolonged pain and distress can be avoided by the use of a 50 per cent nitrous oxide/oxygen mixture, which can also be used during transport to hospital. The analgesic effects are rapidly reversed, which allows the patient to provide a history free from sedative effects of analgesia.¹

Hyoscine butylbromide is a quaternary ammonium anti cholinergic agent. The peripheral effects of which are similar to those of atropine, but weaker and of shorter duration. Hyoscine butylbromide is used in the treatment of conditions associated with gastro-intestinal spasm. The usual dose is 20 mg intramuscularly or intravenously, repeated after 30 minutes if

necessary. It is also given by mouth in doses of 20 mg four times daily, and is claimed to be of value in spasmodic dysmenorrhoea.²

Dicyclomine hydrochloride: is an anticholinergic agent with peripheral effect similar to but much weaker than those of atropine, it also has direct antispasmodic action and a local anaesthetic action. It is used in biliary, gastrointestinal or urinary tract spasm and is given with antacids in the treatment of gastric and duodenal ulcer.³

Dicyclomine is indicated in functional bowel/irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. It is contra-indicated in obstructive uropathy. (for example bladder neck obstruction due to prostatic hypertrophy); obstructive disease of the gastro-intestinal tract (as in achalasia, pyloroduodenal stenosis), paralytic lieus, intestinal atony of the elderly or debilitated patients, unstable cardio-vascular status in acute haemorrhage; severe ulcerative colitis, toxic megacolon/complicating ulcerative colitis, myasthenia gravis.⁴

Phenazopyridine hydrochloride: Symptomatic relief of pains, burning, frequency, urgency, and other discomforts arising from irritation of the lower urinary tract mucosa..... its topical analgesic action may reduce or eliminate the need of systemic analgesics or narcotics. Contra-indicated in renal insufficiency. A yellowish tinge of the skin or sclerae may indicate accumulation due to impaired renal excretion and the need to discontinue therapy.⁵

1. Oxford Text Book of Medicine: 1987: 21.27
2. Oxford Text Book of Medicine : 1987: 12.202
3. Oxford Text Book of Medicine: 1987: 13.172
4. Martindale. The Extra Pharmacopoeia 30th edn: 1993 P. 423.
5. Martindale. The Extra Pharmacopoeia 30th edn: 1993 P. 29.

Dextropropoxyphene hydrochloride (Propoxyphene hydrochloride): is a centrally acting narcotic analgesic agent. It is structurally related to methadone. The potency of propoxyphene hydrochloride is from two-thirds to equal that of codeine....Do not prescribe propoxyphene for patients who are suicidal or accident prone. Prescribe propoxyphene with caution for patients taking tranquillisers or anti-depressant drugs and patients who use alcohol in excess. Tell your patients not to exceed the recommended dose and to limit their intake of alcohol.¹

Prolonged use of higher doses of dextropropoxyphene may lead to dependence of the morphine type. Liability to abuse is reported to be a little less than for codeine side effect.

Pentazocin: is a potent analgesic, which when administered orally is approximately equivalent, on a mg for mg basis, in analgesic effect to morphine. The respiratory depressant effects of pentazocin and its potential for elevating cerebrospinal fluid pressure may be markedly exaggerated in the presence of head injury.

For the relief of moderate to severe pain, 30 mg of pentazocin intramuscularly is reported to be equivalent to about 90-100 mg pentazocin by mouth, about 10 mg of morphine subcutaneously or intramuscularly, or 50 to 100 mg of pethidine intramuscularly. Pentazocin 66 mg intravenously appeared to be a suitable analgesic for patients with a recent myocardial infarction.....Unlike morphine, its use was not generally followed by hypotension, an increase in the respiratory dead-space/tidal volume ratio

or an increase in the difference between alveolar and arterial oxygen tensions.....It was suggested that pentazocin should be used in preference to morphine as an analgesic in patients with myocardial infarction.

The results suggested that dimorphine might be considered to be the analgesic of choice in a situation where rapid relief of pain was essential but pentazocin with its low addiction potential and lower incidence of blood pressure reduction might be the most suitable treatment of pain in patients with a suspected cardiac infarction.

Drugs available in India

Amitriptyline Hcl:

Amiline (10,25,75 mg tab) –Torrent
Amitone (Intas)
Eliwel (Sun Pharma)
Quietel (Alembic)

Amitriptyline Hcl: 10, 25, 75 mg

Amiline (Torrent)
Amitone (Intas)
Eliwel (Sun Pharma)
Quietel (Alembic)

Buprenorphin hcl 0.3 mg/ml

Norphin (Unichem)
Pentorel (Khandelwal)
Tidigesic (TDPL)

Carbamazepine 100, 200, 400 mg

Carbatol (Torrent)
Mazetol (S.G. Pharma)
Tegretol (Ciba-Geigy)
Zen (Intas)

1. Goodman & Gilman 8th edn: 1991 P. 510

Dicyclomine Hcl 20 mg tab
Cyclominol (Noel)
Cyclo-20 (Indoco)

Dextropropoxyphene available only in
combination form with other
analgesics like aspirin, paracetamol

Flavoxalae Hcl
Urispas (Walter Bushnel)

Glyceril nitrate 0.5 mg tab
Angised (B. Welcome)

Hyoscine-N-Butyl Brom. 10 mg
tab and 20 mg/ml inj.
Buscopan (German Remedies)

Pentazocin 30 mg/ml injection
and 25 mg tablet
Fortwin (Ranbaxy)
Pentavon (Jaggson Pal)
Pentawin (Biochem)
Sosegon (Win Medicare)
Susevin (Indoco)

Phenazopyridine Hcl 100 mg tab
Pyridium (Warner)

Sodium Valproate 200 mg tab
Encorate (Sun Pharma)
Epilex (Reckits)
Valparin (Torrent)

RESULT: Dipyrene (NOVALGIN,
BARALGAN etc.) can be replaced by better
tolerated or more appropriate analgesics in all

fields of indication. In many industrialized
countries with a similar health care system,
dipyrene has been banned, without any
restrictions of therapeutical possibilities in the
care of patients being documented, and where
it is not banned, it's use is severely curtailed and
used only in terminal cases.

HYDROXYQUINOLINES (Clioquinols)

Brand	Manufacturer
Lumigyl	Plazma
Novanidagyl	P & B
Stadmed	Stadmed

REASON FOR BANNING : Dangerous.
Causes SMON¹ a painful nerve disease which
causes limb paralysis, blindness and lack of
bladder control. Effective and safer anti-
amoebic drugs are available.

"Clioquinol has caused thousands of cases
of SMON in Japan and elsewhere. A condition
involving continuous pain, paralysis, blindness
and, in extreme cases, death."²

"There is no convincing evidence to
suggest that....clioquinol (is) effective in the
prophylaxis of travellers' diarrhoea."³

"Hydroxyquinolines are active only on
organisms present within the intestinal lumen.
Used alone, therefore, they are active only in the
absence of significant tissue invasion - a
development that cannot be excluded with
certainty even in patterns with asymptomatic
amoebiasis."⁴

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1. SMON : (Sub-Acute Myelo-optic Neuropathy) : See note on late Dr. Olle Hansson
 2. Social Audit. Bad Information Means Bad Medicine. 1982
 3. British National Formulary, 1992 P. 50
 4. WHO Drug Information, January-March, 1978. PDT/D 781-see P. 55 for details
-

Diodohydroxyquin and iodochloro-hydroxyquin have widely and all too often been indiscriminately employed for the treatment of diarrhoea. The use of these drugs, particularly at high doses for prolonged periods is unfortunately associated with significant risk. Administration of diodohydroxyquin in high doses to children with chronic diarrhoea, for example, has been associated with optic atrophy permanent loss of vision.¹

Broxyquinoline has exactly the same properties concerning toxicities and there are cases in Sweden with exactly the same clinical picture as the clioquinol cases. So there is nothing to say that there are any differences in the toxicity of the different halogenated oxyquinolines.²

Antimicrobial drugs are not indicated for the routine treatment of acute diarrhoea. Their indiscriminate use must be discouraged not only because they are often of no value, but they are needlessly expensive and can also be harmful.

It was suggested that the Japanese epidemic might be due to genetic susceptibility but a few similar cases of SMON have been reported from several other countries in association with clioquinol or related hydroxyquinoline derivatives, such as broxyquinoline or di-iodohydroxyquinoline. Oral preparations of clioquinol have now been banned in most countries.³

USED: For diarrhoea and amoebic dysentery.

9. FIXED DOSE COMBINATIONS OF STREPTOMYCIN & PENICILLIN

Brand	Manufacturer
Bistrepen	Alembic
Bistrepen forte	Alembic
Discrysticin-S	Sarabhai
Discrysticin-S Paed.	Sarabhai
Penicillin-Streptomycin	IDPL
Strepto Penicilin	HAL

REASONS FOR BANNING: Dangerous. Streptomycin is used to treat tuberculosis and should be reserved for this purposes only. If combined with other drugs which are not useful for treating tuberculosis. (like penicillin, the combination is used for purpose other than tuberculosis) resistance to streptomycin increases, making it useless for tuberculosis patients. Safer broad spectrum antibiotics are available which do not have this effect.

“Because of its toxicity and tendency to develop bacterial resistance, this drug should be reserved for treatment of tuberculosis and the few other serious diseases for which it is clearly indicated”.⁴

“When Intramuscular injections of streptomycin and penicillin were mixed both drugs lose about 30% of their potency within 30 minutes.”⁵

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1. Goodman and Gilman The Pharmacological Basis of Therapeutics, 8th Edition, 1991 P. 1002
 2. Dr. Olle Hansson, Geneva Press Conference on SMON Proceedings : April 28, 1988, Geneva, P. 25
 3. Martindale : Extra Pharmacopoea 30th edn. 1993 P. 511
 4. Problem Drugs, HAI
 5. Martindale, 28th edition, 1985, P. 1213
-

"Use of Streptomycin in combination with penicillin even for bacterial endocarditis has not been mentioned by Oxford Text Book of Medicine."¹

The dose of Streptomycin in the available combinations is 500mg. per dose which is definitely inadequate when it is to be used in subacute bacterial endocarditis.

"Streptomycin is a drug of choice in the treatment of tuberculosis and should generally be reserved for this use because when used in the treatment of other bacterial infections resistance has been found to develop within 2 to 3 days."²

"Although such strains of **E-Coli** are highly resistant to streptomycin, they are not wide-spread in nature. similarly, only 5% of strains of 64 **Pseud aeruginosa** exhibit such ribosomal resistance to streptomycin. However, up to 50% of strains of enterococci isolated from patients with endocarditis are resistant to high concentrations of streptomycin, and ribosomes from these strains fail to bind the antibiotic. For this reason there is no synergistic effect of penicillin and streptomycin against these strains demonstrable in vitro."³

"Streptomycin is now rarely used except for the treatment of certain types of

streptococcal bacterial endocarditis, tularemia, plague, and as a second-or 'third-line agent for tuberculosis."⁴

Reason why Streptomycin Penicillin fixed dose combination should be banned.

Mixing penicillins with aminoglycosides in vitro has resulted in substantial mutual inactivation, if these groups of antibacterials are to be administered concurrently, they should be administered at separate sites at least one hour apart.⁵

"Among the less common toxic reaction to streptomycin is peripheral neuritis. This may be due either to accidental injection of a nerve during the course of parenteral therapy or to toxicity involving nerves remote from the site of antibiotic administration."⁶

"The administration of streptomycin in parenteral form should be reserved for patients where adequate laboratory and audiometric testing facilities are available during therapy" PDR 49th and 1995 P. 2100.⁷

Streptomycin Penicillin combination is being used for several infections including respiratory infections — this could mask the diagnosis of Tuberculosis thus make Treatment more difficult.

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1. Oxford Text Book of Medicine International Martindale Ltd. Infective Endocarditis. 1984. P. 13 229
 2. Antibiotic Guidelines 5th Edition 1987 prepared by the Standing Committee on Infection Control. Health Department of Victoria.
 3. Martindale : The Extra Pharmacopeia. 28th edition. 1985 P.1101
 4. Ibid. P.1098.
 5. Drug Information for the Health Care Professional Vol. I. USPDI. 15th Edition. 1995
 6. 3. Martindale The Extra Pharmacopeia. 28th edition. 1985 P.1107
 7. Ibid. P. 1105
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GAZETTE AMBIGUITIES

Because of the ambiguous wording of the Gazette Notificaiton of July 23, 1983, it is unclear whether the following drugs are banned or not.

1. CAFFEINE IN TONICS

Most investigators feel that tolerance and limited degree of psychological dependence deveop with caffeine and a withdrawal headache has been described repeatedly.¹

"There is no doubt that a certain degree of tolerance and of psychic dependence develops to the xanthine beverages... The feeling of well-being and the increased performance it affords, although possibly obtained at the expense of decreased efficiency later in the day, are experiences that few individuals care to give up."²

Brand	Manufacturer
Orheptal	Merck
Rapsovin	Raptakos
Mynberrys	Juggat Pharm.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Not reported*

RATIONAL ALTERNATIVES: Omission of caffeine and weeding out of tonics.

2. DRUGS CONTAINING STRYCHNINE

Strychnine is mentioned in most medical text books for its historical value. It was at one time prescribed liberally as a 'tonic'. Its main use has been to kill 'moles' in the field. It has

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1. Goodman & Gilman, 8th edn. 1991, p. 630
 2. Oxford Text Book of Medicine 1987, p. 6.13
-

been exploited deviantly by the ‘Drug Culture’, being ‘shot’ intravenously.¹

Despite the fact that strychnine preparations are less available than formerly, poisoning by strychnine still occurs from sugar coated proprietary cathartics and tonic tablets. There are no pharmacological rationale for this dangerous practice.²

There is no current justificaiton for its presence in any medication.³

3. DRUGS CONTAINING YOHIMBINE

Yohimbine has been used for its alleged aphrodaisiac properties but convincing evidence of such an effect is lacking.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Cyprus, Denmark, Italy, Nepal, Philippines, South Africa, Turkey, Venezuela.

4. DRUGS CONTAINING ARSENIC

EXAMPLE OF COMBINATIONS: Not available.

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED : Italy. Philippines.

SAFER ALTERNATIVE: Drugs without arsenic

5. ANTI-INFLAMMATORY DRUGS WITH VITAMINS

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Bangladesh, Nepal.

RATIONAL ALTERNATIVE; Anti-inflammatory drugs alone.

6. TRANQUILLIZERS WITH VITAMINS

Brand	Manufacturer
Placidox-2	Lupin
Placidox-5	Lupin
Placidox-10	Lupin

EXAMPLE OF COMBINATIONS:

Placidox-10 (Lupin) : Diazepam, Vitamin B₆

COUNTRIES WHERE BANNED, WITHDRAWN OR RESTRICTED: Bangladesh, Nepal.

RATIONAL ALTERNATIVE: Tranquillizer alone.

1. Goodman & Gilman : 8th edn. p. 583
2. Goodman & Gilman : 8th edn. p. 584
3. Goodman & Gilman : 8th edn. p. 582

DID YOU NOT
READ THE
"POSSIBLE SIDE EFFECTS"
WRITTEN IN
SMALL PRINT
ON THE BACK?!

BUT THAT'S
ALL GREEK
AND LATIN
TO ME !!

Stephen

KNOW YOUR MEDICINE ?

The focussing on hazardous, banned and bannable drugs is aimed at creating public awareness about responsible use of medicine.

Very often consumers as well as the prescribing doctors are not aware of the various ingredients and their dosages in a branded pharmaceutical preparation being prescribed and consumed.

Very often prescriptions are given and the side effects of the drugs are confused as being part of the disease and patients unaware of the side effects continue to take the drugs. Many patients even suggest the drugs prescribed to them to others having similar problems e.g. arthritis, asthma etc. Since treatment for both the disorders is for long periods and requires repeatedly often the drugs prescribed once are continued for long to avoid repeated and costly visits to the doctors. Steroids and steroid combinations have been prescribed for both the above conditions, but usually should be for short duration.

As a case study we will look closely at steroids. Steroids can be life saving drugs and have a very important role in medical treatment of certain conditions. They however, continue to be one of the most misused therapeutic category of drugs, as patients tend to feel better even while infection continues within the body.

It is important for consumers to be aware whether the brand names of drugs are taking contain steroids, when should they be taken and in how much dose, how often and for how much duration, how and when to stop the drugs.

Sometimes steroids are also being given in the name of Ayurvedic drugs. Awareness about the medicines being taken, precautions to be used and side effects to be watched out for, is very essential. Not with a purpose of scaring but with a purpose of alerting are the various side effects being mentioned. To avoid the avoidable drugs to know and recognise potential problems with those drugs that are really needed is an important principle of

rational drug use.

Unless considered life saving, systemic administration of corticosteroids is contra-indicated in patients with peptic ulcer, osteoporosis, psychosis or severe psychoneuroses and they should be used only with great caution in the presence of congestive heart failure or hypertension in patients with diabetes mellitus, epilepsy, glaucoma, infectious diseases, ocular herpes simplex, chronic renal failure, and uraemia and in elderly persons.

Patients with active or doubtfully quiescent tuberculosis should not be given corticosteroids except very rarely, as adjuncts to treatment with antitubercular drugs. Patients with quiescent tuberculosis should be observed closely and should receive chemoprophylaxis if corticosteroid therapy is prolonged.

Corticosteroids are contra indicated in the presence of acute infections, because of interference with inflammatory and immunological response. Patients receiving corticosteroid therapy are more susceptible to

infection, the symptoms of which moreover may be masked until an advanced stage has been reached. Patients and relatives must be given full details of corticosteroid administration, implications of the therapy and precautions to be taken.

Concurrent administration of barbiturates, carbamazepine, phenytoin, primidone or rifampicin may enhance the metabolism and reduce the effects of corticosteroids. Administration of steroids with potassium depleting diuretics, such as thiazides or furosemide may cause excessive potassium loss.

There may be increased incidence of gastrointestinal bleeding and ulceration when corticosteroids are given with non steroidal anti-inflammatory agents.

Corticosteroids should not be applied to ulcers of the leg and long term topical use is best avoided especially in children and caution is required in using local application of corticosteroids in eye disorders.



HAZARDOUS DRUGS

THE CURRENT SITUATION

It is possible to go into your local chemists's shop today looking for something to treat a simple headache, a remedy for diarrhoea, something for rheumatism, a tonic and a pregnancy test and come out with one drug that could blind and paralyse you for life, another which could deform a baby still in the womb, one more which could make your young daughter grow a moustache, and another couple of drugs which could give you a serious and often fatal blood disease. Are there no alternatives? Is it really necessary to take such risks?

Allopathic medicine recognises the potential harmful effects of drugs. Very few can be taken without any side-effects, even in therapeutic doses. In deciding which drug to use, (if at all) it is important to compare the possible adverse effects the drugs may produce, and weigh them against each other, and against the risk of taking no drug at all, using alternative systems of medicines. Most

important of course in the first place, is an effort to prevent the disease.

DANGEROUS DRUGS WHICH SHOULD BE SEVERELY RESTRICTED

Many drugs are useful only in certain indications—they are unnecessarily harmful in others.

Anabolic steroids (synthetic male hormones) form one category of drugs which are often used to treat conditions for which they are both useless and dangerous. These drugs are only useful as supportive therapy in treating certain rare conditions such as aplastic anaemia (bone marrow shut down), where the patient is very seriously ill. Instead, anabolic steroids are widely sold as tonics and growth stimulants for malnourished children - they are even listed under the 'Nutrition' section of the commercial drug prescribing guides. As tonics, they are not

only useless but dangerous. Anabolic steroids can actually stunt growth in children by prematurely closing the epiphyses (the growing ends of bones). Moreover, the sexual development of children who take these 'special' tonics can be seriously disturbed. Young girls can develop masculine characteristics such as deepening of the voice and facial hair, which are all the more distressing since these effects are irreversible. The best treatment for poor growth or underweight is of course good nutritious food, not expensive drugs, yet well-meaning parents and ignorant doctors continue to give anabolic steroids to help the child grow, oblivious of both the dangers and the futility. Furthermore, a malnourished child very often comes from a family which can least afford to waste its meagre income on expensive medicines.

Dangerous drugs like anabolic steroids which are advisable only in specific life-threatening situations should be very severely restricted to only those situations. Some of the other drugs which are very commonly misused are chloramphenicol and streptomycin.

In the case of **Chloramphenicol**, a patient with typhoid fever will be more likely to survive if given the drug. Chloramphenicol was an effective and cheap drug for typhoid, though potentially hazardous. But someone with a less serious bacterial infection would be unwise to risk the hazards associated with this drug when a safer alternative, such as co-trimoxazole or ampicillin, will cure the infection just as effectively. A child with diarrhoea who is given chloramphenicol is facing the risk of possible fatal side-effects while gaining no benefit.

Usage of **Chloramphenicol-Streptomycin** combination can cause diarrhoea because of super infection due to change in gut flora.

Misuse of antibacterials for the common viral childhood diarrhoeas and other trivial problems for which antibacterials are not indicated has led to emergence of drug resistance.

A study of multiple drug resistance in isolates of salmonella in India over the period 1972-78 indicated that since 1975, appreciable numbers of serotypes from human and non-human sources had emerged with multiple resistance to about 2006 antimicrobial agents. Isolates of *S.typhi* uniformly resistant to chloramphenicol, streptomycin, sulfafurazole and tetracyclin had been obtained.¹

The casual and unnecessary use of antibiotics not only harms the individual - it creates havoc in the population as a whole. Thousands of people died in Mexico in 1975 from a typhoid epidemic quite unnecessarily. Chloramphenicol had been used carelessly over the year for trivial infections like diarrhoea, allowing resistance to build up. When the outbreak occurred it was found that chloramphenicol used mainly in typhoid was quite useless.

In the *Shigella* dysentery endemic in West Bengal a few years ago, over 2000 people died due to resistance having emerged to most of the commonly used antibiotics. By the time the fact that drug resistance had emerged was recognized, it was too late. The answer is not more and more exotic costly antibiotics, but responsible use of what we have, leaving the

¹ K B Sharma et al, *J. Antimicrob Chemotherapy* 1979 S. as quoted in Martindale 28th edn. 1985. p 1139

exotic ones for special situations. In a country like ours, where tuberculosis is a major cause of suffering and mortality, the casual use of **streptomycin** (an essential part of low cost TB treatment) is threatening the lives of thousands. Streptomycin is commonly given in fixed-dose combinations with penicillin or with chloramphenicol for trivial infections which could be treated better in other ways. Through this casual use, TB bacilli are given ample opportunity to develop resistance to streptomycin and the number of TB patients who fail to respond to treatment is increasing daily. The high cost of treating all cases of tuberculosis with expensive drugs like rifampicin makes such treatment an impossibility. It is imperative that we limit the use of streptomycin to cure diseases for which streptomycin is intended.

Hazardous drugs with limited usefulness should be very severely restricted to their specific uses. The present practice of individual patients being unnecessarily exposed to serious and sometimes fatal side effects, when safer treatment is available, should be stopped.

DANGEROUS AND IRRATIONAL DRUGS WHICH SHOULD BE BANNED

There are some drugs which are never useful—their benefits never outweigh their harmful effects under any circumstances. This is either because safer alternatives are available, or because the drug is simply useless, or both.

Hydroxyquinoline Clioquinol is another highly-selling but dangerous drug which has escaped the ban. It is used to treat diarrhoea and is commonly known as the 'Khaki tablet', the colour of the leading brand, then

Enterovioform. Eleven thousand people in Japan alone were afflicted with the very serious side-effects of this drug. Intoxication with Clioquinol has been reported from the USA, Canada, France, Switzerland, Federal Republic of Germany, Austria, Sweden, Denmark, Netherlands, Finland, Belgium, Poland, Spain, Italy, Iran, India, Indonesia, Brazil, Israel, Lebanon, Argentina, Australia.

Clioquinol damages the nervous system, and can result in paralysis, blindness and loss of bladder control, often accompanied by great pain in the limbs. It was taken up in the courts and after a long hearing with evidence from internationally renowned experts, the verdict was given (1971) that the suffering of these victims was due to clioquinol. The drug companies (Ciba Geigy, Tanabe and Takade) were found responsible for sales of these drugs while failing to inform doctors and the public about their hazards.

Very soon afterwards, other countries stopped using the drug, which has now become obsolete in many parts of the world. The Government of India did likewise, and banned clioquinol (D.O.X. 19013/8/81-D August 13, 1982).

However it was not long before the ban was superseded by another Gazette Notification (DO No.X 11014/1/83-DMSOPFA July 23, 1983) which excluded from the ban all preparations intended to treat diarrhoea, and those intended for external use (clioquinol is safe for external use). So the purpose of the original ban (to prevent the suffering caused by clioquinol) was entirely defeated and diarrhoea sufferers continue to risk their health by taking this unnecessary drug. Again the people who suffer the most from diarrhoea (those who do

not have safe drinking water, sanitation and enough food) are those who can least afford the harmful and debilitating effects of clioquinol. Ironically, they remain unaware of the cheapest and most effective treatment, oral rehydration solution, made at home from sugar, salt and water.

Analgin is another dangerous drug recommended for banning (as a fixed dose combination) by the Drug Consultative Committee in 1980. However, analgin is one of the most popular over-the-counter drugs, and is far better known to the general public than its safer and cheaper alternative, aspirin. It is the sodium sulphonate of amidopyrine, banned by the Government in 1983, and can cause the same blood disease, agranulocytosis (see glossary), which is often fatal. Since these hazards have been discovered, amidopyrine and analgin have almost disappeared from other countries and become obsolete. Even standard pharmacology textbooks refer the reader to earlier editions to find information on these drugs.

Analgin as an analgesic, antipyretic and anti-inflammatory agent carries far more risk of serious side effects than paracetamol or aspirin, given properly, which are just as effective.

The sub-committee of Drug Consultative Committee also recommended in 1980 that fixed dose combinations of analgin be weeded out. The Drugs Technical Advisory Board in 1982 deleted this from their recommendation. Analgin combinations were recommended for being weeded out by the subcommittee of the Drug Consultative Committee under the Chairmanship of Dr. Patel, Commissioner, FDA, Gujarat, which met in 1988. Analgin combinations were banned only in 1995.

Analgin and analgin combinations with anti-spasmodics have been ironically excluded from the ban.

Another drug which has achieved international notoriety, but which is still commonly available in India, is **oxyphenbutazone**. The Government has not yet attempted to ban it. The firm which discovered the drug in the 1950s, Ciba-Geigy, has withdrawn from the world market this product, sold under the brand name Tanderil. It has caused over a thousand deaths worldwide, and has been replaced by far safer alternatives. Its close relation, phenylbutazone which has very similar side-effects, has been recommended by the Drug Control Authorities of India only for ankylosing spondylitis and acute gouty arthritis and even then, only as a drug of second choice. Yet, sales of oxyphenbutazone and phenylbutazone under several brand names continue unrestricted.

The outright banning of clioquinol, analgin and oxyphenbutazone and phenylbutazone could only lead to an improvement in the health of the people of India.

IRRATIONAL DRUGS : ATTEMPTS AT BANNING DRUGS

The irrational drugs on the market are too numerous to list here. Most of the 60,000 formulations available are combinations of two or more drugs, with very few exceptions (e.g. the oral contraceptive pill).

During the last hearing on 8th May 1994, the Supreme Court asked the petitioners (Drug Action Forum, Karnataka All India Drug Action Network, DSF) to submit the list of drugs that the petitioners want to see banned.

The list of irrational drugs to be banned is too long since a majority of the drugs available in the Indian market are irrational. This is indicated by all the studies that have been carried so far of different types of drugs available in the market - tonics, antidiarrhoeal, cough and cold preparations, iron-haemoglobin tonics, over the counter drugs etc. It is not expected of the Supreme Court to undertake the huge technical task of going through the irrationalities of each category of drugs. The Central Government has already appointed in 1987, an 'Expert Committee' on weeding out irrational/harmful/sub-therapeutic drugs. It may be noted that the government can ban not only hazardous drugs but under Section 26 A of the Drugs & Cosmetics Act, 1940, the government can ban those drugs which 'do not have the therapeutic value claimed for them or contain ingredients and in such quantity for which there is no therapeutic justification'. However, because of this Expert Committee, so far, only irrational antidiarrhoeals have been recently banned during last 6-7 years. The Supreme Court should give a directive to this committee that

1. The Committee should function far more effectively and efficiently, since hundreds of drugs belonging to dozens of categories need to be evaluated to weed out the irrational/harmful/subtherapeutic drugs and drug combinations.
2. The Committee should accept the following principle for weeding out drugs - all drugs or drug-combinations, which have not been recommended by standard text books of pharmacology or medical sciences or by WHO, should be banned. This principle is quite scientific and practical. The rationale behind this principle is:

Firstly, poor countries like India cannot afford the luxury of unscientific formulations not recommended by standard textbooks of pharmacology or by WHO. A study has estimated that 63% of the money spent by patients on drugs is wasted due to irrational drug use.

Secondly, the unnecessary drug or drug in a wrong dose in these unscientific drug formulations pose an unnecessary health hazard in the form of iatrogenic diseases.

Thirdly, it is almost impossible for the drug-authorities to do the quality control testing of these hundreds of formulations, containing thousands of different ingredients in different proportions. So is the case with the monitoring of their prices.

The Supreme Court, in its judgement in the case of Vincent Penikulangara Vs Union of India (1987, 2 SCC, p-165), had directed the government that there should be adequate representation on behalf of the consuming public on the Drugs Technical Advisory Board. Prompt action should be taken to suitably amend laws to authorise such representation both on the Technical Board as also the Consultative Committee. The government has not followed up this recommendation of the Supreme Court. The Supreme Court should order the government to carry out this directive immediately and include one of the experts from the petitioners/co-petitioners on the Expert Committee.

There is no need to carry out clinical trials to assess the rationality, effectivity in 'Indian condition' of any particular drug or drug formulation. Like wise there is no need to assess

the incidence of adverse effects of a particular drug (like say analgin or clioquinol) in 'Indian Conditions' before banning the same. Sufficient international evidence is available to assess the efficacy and/or safety of these drugs. Genetic differences should not be a cause to withhold banning of a drug if it is already banned by the advanced countries or by the parent research companies. Secondly, if clinical trials were not conducted to decide the efficacy of these drugs in 'Indian conditions' while introducing these drugs, why should clinical evidence of hazardousness be sought before banning the drugs?

Particular care should be taken by these committees and by the Drug Controller of India, that the recommendations and the Gazette notifications should be precise and not have ambiguities of wording to keep loopholes for the companies to exploit. Such loopholes have also delayed the implementation of the ban-orders in the past.

No prior notice should be given to drug companies before the ban notification. Such prior notice was given by the Drug Controller of India per his circular dt 8th February 1994, about the impending ban on irrational antidiarrhoeals. In this circular, the Drug Controller has clearly mentioned that the letter was sent to enable the drug companies to plan their marketing strategies, so as to withdraw the stocks of subject drugs from the market before the Gazette notification is notified. This is an objectionable practice. Once the Drug Controller is satisfied that particular categories of drugs need to be banned, no prior notice should be given to the manufacturers about the impending ban. It is sufficient to give 1 - 2

months for the manufacturers and stockists, chemists and pharmacists to withdraw their stocks after the ban order. In case of irrational antidiarrhoeals, more than seven months have passed after this notice (8 Feb 94) and the gazette notification has not been issued till mid September 94. Besides prior notice can be ill-used by manufacturers to create legal hurdles in the ban order.

RATIONAL COMBINATIONS

FIXED DOSE COMBINATIONS INCLUDED IN THE WHO LIST¹

Benzoic acid	+ Salicylic acid
Carbidopa	+ Levodopa
Ethinylestradiol	+ Levonorgestrel
Ferrous Salt	+ Folic Acid
Isoniazid	+ Rifampicin
Isoniazid	+ Thiacetazone
Neomycin	+ Bacitracin
Sulfadoxine	+ Pyrimethamine
Sulfamethoxazole	+ Trimethoprim

With very few exceptions (e.g. the above) fixed dose combinations are unnecessary: single ingredient drugs are just as effective and cheaper. It is impossible for doctors to remember the ingredients and proportions of so many formulations and this leads to confusion in prescribing, and increases the chances of drug interaction. On top of this, reformulations are made without any systematic way of informing the doctors as well as chemists of the change.

Many of these combinations are irrational in themselves. **Anti-diarrhoeal** drugs often

1. WHO Technical Rep. Ser. 825, 1992.

contain ingredients which are hazardous not only present in sub-therapeutic amounts, but which are useless in the treatment of diarrhoea anyway.

Very few **tonics** include the correct proportion of vitamins and minerals, although they often contain alcohol. Food is the best way to overcome vitamin or mineral deficiency. There are tonics in the market even for newborn babies, when all that a baby needs for the first four months of life is contained in exactly the right proportions in mother's milk, even if the mother is malnourished herself.

Food substitutes like Glucon-D are widely sold at high prices even though glucose and vitamin D are far more cheaply obtained from food and sunlight.

Painkillers are often combined with an amount of caffeine too small to have any therapeutic effect on the human body, and is not useful in relieving pain, either. The Gazette Notification ban included the useless combination of analgesics with vitamins. People are paying higher price for irrational and unnecessary additions to the drug they need.

The arrangement obviously holds no medical benefit whatsoever, and only leads to the exploitation of those who have very little money to pay for their medicines, and next to no information on which medicine to choose. Many poor villagers buy a few tablets at a time, and the difference of 50 paise to 5 paise per tablet is a very real difference to them. There are many other instances of irrational combinations of more expensive and sophisticated drugs.

Wastage of scarce resources is not only taking place on an individual level but at a na-

tional level. With continual shortages of essential drugs in our country, it is shameful to be using our well-developed pharmaceutical industry to produce such huge quantities of irrational and useless combinations. Banning such preparations along with hazardous drugs, and encouraging the production of those medicines which we do need, would be a big step towards rational and people-oriented health care.

BANNED DRUGS

WHEN IS A BANNED DRUG NOT BANNED?

Firstly, when the Government decides (in effect) to lift the ban, as in the case of clioquinol. (Hydroxyquinoline)

Secondly, when the drug companies who stand to lose from the ban, obtain a stay order on it and Government itself fails to vacate the stay order.

Thirdly, when the ban is diluted, so as to leave out some hazardous drugs.

The banning of steroid combinations (see P. 24) excluded steroids intended for asthma. The result was that steroid combinations previously indicated for other illnesses were suddenly recommended for asthma, while usage for earlier indications continued.

Fixed dose combination of chloramphenicol was recommended for banning by DCC in 1980. It was diluted by the DTAB to Chloramphenicol combination, excluding Choloramphenicol and

Streptomycin combination.

Fourthly, when a ban order is ambiguously worded, leaving room for loopholes. The Gazette Notification of July 1983, failed to specify whether a drug would be banned only if all ingredients or if any of the combination of ingredients were present. eg. Yohimbine strychnine in Testosterone in tonic as in category 5 Gazette Notification.

Failure to specify meaning of steroid combinations as to whether it would include anabolic steroids and listing of the specific drugs.

Wording the Gazette Notification in such a way that injectable preparation is left out when the preamble clearly states that the formulations are harmful and have no therapeutic value. But only oral dosage forms are mentioned in the section having legal status. Thus giving an impression that all formulations are banned (injectables and tablets) yet banning only the latter. eg. High dose oral formulation.*

Fifthly, when the ban order is not enforced. When the legislation is inadequate. eg. The 22 categories of banned drugs could not be banned till the Drugs and Cosmetics Act was amended following which alone was the Gazette Notification issued in July 1983.

When the ban order is issued in a

Gazette Notification and no effort is made to use the government media e.g. AIR, Doordarshan as well as major national dailies to publicise the drugs and the brands involved.

When name of brands and the manufacturers of the banned drugs is not made public to prevent doctors from prescribing and consumers from consuming them.

When authorities concerned fail to ensure withdrawal of stocks from the manufacturers and the market.

When authorities concerned fail to seriously monitor the continued sales of banned drugs.

Sixthly, when authorities concerned consistently fail to punish those who violate the ban orders.

An urgent screening and listing of all the drugs in the market is required.

Identification of hazardous and also irrational and non-essential drugs is required.

Withdrawal of these drugs should take place immediately.

Deterrant punishment of those who continue to sell banned drugs and challenge the decision of the Drug Controller and the Drug Consultative Committee.

Note* This was later changed to include injectable preparations also after protests



DRUGS OF DOUBTFUL EFFICACY

Just a few examples are being given to highlight the need for unbiased information and need for restriction of drugs with little or no therapeutic value.

1. Cerebral Vasodilators

Brand

Arlidine (Nylidrine Hcl)

Clendal (Cyclandalate)

Complamina (Xanthinol Nicotinate)

Cyclasyn (Cyclandalate)

Cyclospasmol (Cyclandalate)

Duvadilan (Isoxsurpine Hcl)

Flexital (Pentoxifylline)

Flowpent (Pentoxifylline)

Kinetal 400 (Pentoxifylline)

Martispasmol (Cyclandalate)

R.B.Flex (Pentoxifylline)

Suprox (Isoxsurpine Hcl)

Tidilan (Isoxsurpine Hcl)

Trental & SR (Pentoxifylline)

Manufacturer

U.S. Vitamin

Sun Pharma

German Remedies

Cipla

Elder

Duphar

Sun Pharma

Boots

Protec

M.Harris

Torrent

Swift

Jaggat

Hoechst

CEREBRAL ACTIVATORS do not have dilatory action on the cerebral arteries, these should be used with extreme caution in patients with severe obliterative coronary artery or cerebral vascular disease, since there is a possibility that these diseased areas may be compromised by vasodilatory effects of the drug elsewhere. Niacin may potentiate hypotensive drugs, phenothiazine derivatives and inactivate fibrinolysin.

Brand	Manufacturer
Cerecetam (Piracetam)	Intas
Cereloid (Ergoloid mesylate)	Sun Pharma
Encephabol (Pyritinol)	Merck
Ginkocer (Ginkgo biloba)	Ranbaxy
Glutaneurol (L + glutamic acid)	Francho Indian
Hydergine (Codelergocrine Meysylate)	Sandoz
Neurocetam (Piracetam)	Brown & Burk
Nimodip (Nimodipine)	U.S. Vitamins
Nootropil 800 (Piracetam)	Unisearch
Normabrain (Piracetam)	Torrent
Piracetam (Piracetam)	Croydon
Trivastat LA (Piribedil)	Serdia
Vasotop (Nimodipine)	Protec

Adequate data is not available to justify their use as cerebral activators.

2. APPETITE STIMULANT (CYPROHEPTADINE & BUCCLIZINE HCL) PAEDIATRIC FORM

Brand	Manufacturer	Brand	Manufacturer
Apilysin	Diamond Drug & Chem	Apetamine	Tablets (Ind)
Aptagrow	Gracure Pharma	Apetone	Synokem
Appetin	Health Care Formulation	Cyp L	Albert David
Apetox	Kumaayun	Cyprovit	Biocare
Apisol	Rays Lab	Cydine	C.F.L. Pharma
Apectin L	Redson	Ciplactin	Cipla
Aptaup	Wings Pharma	Cylip oral	Dolphin
Aptone	Mesco	Cyaptin	Duckbill Drugs

Brand	Manufacturer	Brand	Manufacturer
Cypon	Geno	Osactin-LP	Osho Pharma
Cypsino	Jeps Pharma	Oraxin	Centaur
Cypromed	Medico Labs	Paritex	Jhones & Wexoes
Cyproheptadine Hcl	Medochem	Perikon	Kon Test
Cyproheptadine Hcl	Sugra Pharma	Practin	Merind
Cyprid	T.M. Thakore	Practin EN	Merind
Cypromed	Tosc	Peritol	Themis
Cyprowal	Wallace	Peritol G	Themis
Eptocal	Kamron Labs	Step Up	Emcee
GI	Glyco	Ste Actin	Stephan
Heptadin	Lancet Remedies	Udactin	Universal Drug
Lycyp	Brawn	Grohite	Welbeck
Longifene	Uni-U.C.B.	Higrochem	Chemitech Drug
Merizyme drops	Mercury	Lycotone	Ace Lab
Magnadyn	Pfimex	La Cyp	La Cure

These should not be used in newborn or premature infants. Overdosage particularly in infants and children, may produce hallucinations, central nervous system depression, convulsions and death. May diminish mental alertness.

3. Digestive Enzymes

Digestants are drugs that supposedly promote the process of digestion in the gastrointestinal tract in conditions characterised by a lack of one or more of the specific substances that function in the digestion of food. While a number of products are marketed, including many bizarre mixtures of components,

the only preparations that merit consideration are those of pancreatic enzymes.¹

Since acid and peptic activity in the stomach can destroy the pancreatic enzymes, enteric-coated tablets are sometimes used. However the coating may prevent delivery of the enzymes in the duodenum.²

Amylase is used in the production of pre-digested starchy foods and for conversion of starch into fermentable sugars in the brewing and fermentation industries. An alpha-amylase has also been suggested for use as an adjunct to standard therapy in the treatment of inflammation and oedema but is of unproven value.³

1. Goodman & Gilman 7th edn. p. 989

2. Goodman & Gilman 7th edn. p. 990

3. Martindale pp 645

Pancreatin is given by mouth in conditions of pancreatic deficiency such as combizym (inner layer, pancreatic enzyme, outer layer amylase, cellulose, hemicellulose, and protease). Combizym compositum, cotazym B, Enzypan, Phazyme preparations containing pancreatin claimed to relieve discomfort caused by dietary imbalance, are of doubtful value.¹

In most of the preparations given under, the concentration of amylase, papain, pepsin or pancreatin is very inadequate and most of them are not stable in acid medium. Particularly liquid enzymes, once reconstituted are not stable for more than 24-48 hours and as such are not rational.

Most of the enzymes viz. diastase, fungal diastase are inactivated in the acidic medium of the stomach. These enzymes are hydrolysed when they come in contact with water. Hence all the liquid enzyme preparations become useless when reconstituted or when given in liquid form.

Brand		Manufacturer
Aminozyme	-	Stadmed
Aristozyme	-	Aristo
Bestozyme	-	Biological Evans
Digeplex	-	Rallis
Digeplex-DS	-	Rallis

Dizytone	-	Unichem
Brand		Manufacturer
Genozyme	-	Geno
Lupizyme	-	Lupin
Merizyme	-	Mercury
Neopeptine	-	Raptakos
Vitazyme	-	East India

4. Clofibrate in Cardiology

In a large prospective study involving 5000 patients in a clofibrate treated group and 5000 in a placebo-treated group followed for an average of five years on drug or placebo and one year beyond, (the WHO study) there was a statistically significant 36% higher mortality due to noncardiovascular causes in the clofibrate-treated group than in a comparable placebo group. Both studies demonstrated that clofibrate users compared to nonusers have twice the risk of developing cholelithiasis² and cholecystitis³ requiring surgery. Because of the hepatic tumorigenicity⁴ of clofibrate in rodents (rats) and the possible increased risk of cholelithiasis, and because there is no substantial evidence of beneficial effect on cardiovascular mortality from clofibrate, this drug should not be used for the routine treatment of elevated blood lipids for the prevention of coronary heart disease.⁵

-
1. BNF No. 5, 83, 62
 2. Cholelithiasis - stones in the gall bladder
 3. Cholecystitis - inflammation of the gall bladder
 4. Tumorigenicity - increased chances of developing tumors
 5. PDR : 1986 p. 613
-

ATTEMPTS AT BANNING HAZARDOUS DRUGS

CASE STUDY I

HIGH DOSE EP DRUGS

The High Dose EP drugs have been commonly misused both as hormonal pregnancy tests and as early abortion agents. They contain very high doses of the hormone oestrogen, which has a harmful effect on the foetus, especially during the first three months of pregnancy. As a pregnancy test, EP Drugs are not reliable; producing a false positive rate of 18 percent. As an abortion agent, too, they are not effective. If a woman who takes these drugs for either purpose is in fact pregnant, there is a much higher risk that she will give birth to a deformed baby. It is because of this association of congenital malformation that the drug has been withdrawn in several countries and several companies have withdrawn their products.

After a concerted campaign by consumers, health and women's groups who were part of All India Drug Action Network, (amongst the organisations that played a major role in the

E.P.campaign were ACASH, Arogya Dakshata Samiti, Medico Friends Circle, Drug Action Forum, West Bengal. Federation of Medical Representatives Association of India, Saheli Women's Forum and many many others) led by VHAI in 1982, the Government of India finally banned EP drugs (12-48/79-D.O. June 21/22, 1982). This was based on recommendations for the drug ban by Indian Council of Medical Research. Reasons given were as follows:

- safer alternatives exist,
- the drug is grossly misused,
- the drug has been banned in several countries on grounds of safety.

Almost immediately, the pharmaceutical firms producing high dose EP drugs - Organon, now renamed Infar (which produced menstrogen); Unichem (which produced the brand leader, EP Forte) and Nicholas which produced cyclenorm went to the courts in Calcutta and Bombay respectively challenging the ban order not only on the grounds that their products were safe and essential but on the

technicalities relating as to whether the Drug Controller of India or the State Drug Controller should be the authority to ban drugs, and that banning was a violation of their right to trade. Ironically, Menstrogen, a product of Infar (Organon) which challenged the ban order, was not even allowed to be registered in the parent country i.e. Netherlands.

EP case was a case of DOUBLE STANDARDS.

1983— Writ Petition was filed by Dr. Vincent Panikulangara in Supreme Court to seek stoppage of sales of banned drugs. Dr. Vincent Panikulangara's writ petition No. 3492 of 1983. In his application for hearing as amended on 7th February, 1983 under article 32 of the Constitution, he had asked the directions in public interest for the banning of import, manufacture, sale and distribution of such drugs which have been recommended for banning by the Drug Consultative Committee and he also asked for cancellation of all licenses authorising import, manufacture, sale and distribution in respect of such drugs. He also asked the Central Government to constitute a high power authority to go into the hazards suffered by the people of the country on account of such hazardous drugs being in circulation and to suggest remedial measures including award of compensations.

1986— November. Supreme Court ordered public hearings to give an opportunity for consumers and those affected to present their views.

PUBLIC HEARINGS

1988— February, 5th - 1st public hearing in Madras,

April, 10th - 2nd public hearing in Delhi,

July, 10th - 3rd public hearing in Calcutta,

July, 14th - 4th public hearing in Bombay,

— July, 30th decision on High Dose EP drug, 6 months extension asked by the Drugs Controller of India ICMR expert committee and DTAB consulted again, both recommended banning of the drug.

— 15th June through Gazette Notification No. 330 formulations of high dose EP banned.

— 30th June the public came to know of this ban through newspaper reports.

Efforts by consumer and health groups.

Consumer and health groups requested the drug control authorities and Ministry of Information & Broadcasting:

- to get stocks of banned drugs withdrawn, to ensure that the names and brands of the manufactures are announced over AIR, Doordarshan, Newspapers and Magazines to warn chemists, doctors and consumers.
- to recommend to medical professionals alternatives and rational management for pregnancy testing, secondary amenorrhoea etc.
- make low cost, safe, easy to use pregnancy tests available as part of mother and child health and for self-use by women.

On finding that high dose EP drugs even after being banned, were being sold freely, on 26th July 1988, the Association of Consumers Action for Safety (ACASH) filed Writ petition No.4/27 of 1988 in Bombay High Court,

against the Commissioner of Food & Drug Administration of Maharashtra State to withdraw all stocks of these drugs, and warn the public of the brands of banned drugs.

THE GAZETTE OF INDIA

EXTRAORDINARY

PART II - SECTION 3 - SUB-SECTION (I)

PUBLISHED BY AUTHORITY

NEW DELHI, WEDNESDAY, JUNE 15, 1988 JYAISTHA 25, 1910

MINISTRY OF HEALTH & FAMILY WELFARE

NOTIFICATION

NEW DELHI, the 15th June, 1988

G.S.R. 700 (E). - Whereas the Central Government is satisfied that the use of highdose formulation of Oestrogen and Progesterone is likely to involve risk to human beings and such formulation have no therapeutic justification and it is necessary and expedient in the public interest so to do;

Now, therefore, in exercise of the powers conferred by section 26-A of the Drugs and Consmetics Act. 1940 (23 of 1940), the Central Government hereby makes the following further amendment in the notification of the Government of India in the Ministry of Health and Family Welfare No.G.S.R.578(E), dated the 23rd July, 1983, namely:-

In the Table appended to the said notification, after serial number 26 and the entries relating thereto the following serial number and entries shall be inserted namely:-

"27 Fixed dose combination of Oestrogen and Progestin (other than oral contraceptives) containing per tablet estrogen content of more than 50 mcg. (equivalent to Ethenyle Estradiol) and of progestin content of more than 3 mg (equivalent to Norethisterone Acetate).

[No. X-11018/1/88-DMS & PFA]

J. VASUDEVAN, Jt. Secy.

Note: - Government of India Ministry of Health and Family Welfare Notification No.C.S.R. 578(E), dated 23-7-01983 was amended by the following notification published in the Gazette of India Extraordinary, Part II Section 3 (i) namely:-

Finding that the high dose EP injections continued to be sold, as an amendment it also asked for banning of injectable preparations along with tablets (which was expected & seemed obvious on looking at the Gazette Notification). The ambiguity of the wording in the Gazette Notification became obvious. So while the public going by the wording of the Preamble of the Gazette Notification and the newspaper reports, took it for granted that all formulations above the dosage mentioned were banned, while the manufacturers seemed well aware of the loophole of the ban that injectables would be permitted. Why else would Unichem stop production of the tablets in April and continue manufacturing injections even after issuing of the ban order in June? If only tablets were to be banned and injectables permitted, why was it not specified in the ban order in the first place?

The Judgement

The following injectable preparations were mentioned in the Government counsel's submission. Existence of the latter two was not known to many.

Brand	Manufacturer
Menstrogen Forte	Infar
E.P.Forte	Unichem
Cyclenorm	Highland Pharma
S.G.Forte	Sigma

It was obvious that in the absence of the list of the brands of banned drugs, (which was unavailable). It was impossible for the ban to be implemented. While on one hand there has been total unwillingness to accept a generics policy in sales of drugs (as has recently been passed in the Philippines under Aquino) on the other

hand, when it comes to **BANNING** sales of drugs, there is total unwillingness to inform the public about the brands of banned drugs.

High Court (Justice Lentin) stated that the injectable preparation will also remain banned till a convincing reason is given by the Drug Controller of India as to why they should not be also banned, along with the tablets. All stocks in Maharashtra were ordered to be withdrawn. Several chemists shops were raided. In September 1988 Drug Controller of India informed the other states about the Maharashtra High Court's judgement, about stalling production and sale of injectables till final judgement is given.

January 1989 Tablets and injectable preparations of high dose EP drugs continued to be sold in different parts of the country. Complaints had been made to both state and central drug control authorities.

It seemed an Expert Committee was again be formed to review whether injectable preparations should be banned or not. After the public hearings and after the Gazette Notification, whether an Expert Committee was really needed, was a question that a large number of consumer and health groups were asking. If it takes almost a decade to ban a single drug, how long will it take to remove other hazardous and irrational drugs?

The injectable preparation of EP drugs were ultimately banned due to absence of any form of market surveillance system. Sales of such drugs continues unrecognized or underestimated. Sales of Combinations like E.P. Forte (Ergot + Progesterone), D.P. Forte

(Ayurvedic preparation) Oestrogen Progesterone, put separately but in the same drug pack have been reported.

CASE STUDY II

CHLORAMPHENICOL-STREPTOMYCIN AND STEROID COMBINATIONS

- 1979 Screening 34 categories of fixed dose combination drugs took place.
- 1980 Fixed dose combinations of chloramphenicol and fixed dose combinations of steroids recommended for immediate withdrawal by the Drug Consultative Committee.
- 1981 From banning all fixed dose combination of steroids, the decisions was diluted to exclude those combinations used for bronchial asthma. As expected, all fixed dose combinations of steroids changed their indications, to include bronchial asthma on paper, but their misuse for all conditions continued in reality.
- 1983 Gazette Notification issued banning fixed dose combinations of chloramphenicol (except chloramphenicol - streptomycin combination) and fixed dose combinations of steroid (except those used for bronchial asthma).
- 1986 Nation's New Drug Policy formulated. A sub-committee of the Drug Consultative Committee was formed to review the fixed dose combinations and weed out irrational and hazardous drugs. The sub-committee under the Chairmanship of Dr. M.A. Patel,

Commissioner of Food and Drug Administrator, Gujarat recommended the withdrawal of chloramphenicol and streptomycin combinations.

3.11.88 Under Gazette Notification, fixed dose combinations of chloramphenicol-streptomycin and of steroid combinations (even for bronchial asthma) were banned.

1988 Stay orders against the ban on chloramphenicol-streptomycin combination was obtained by Lyka and Deys and by Roussel in the case of steroid combinations.

1988 Banned

February 1989: Whose responsibility is it to ensure that the Stay Orders against these bans are vacated at the earliest? Banned drugs are freely sold. No effort is made to inform chemists, doctors and consumers as to why these drugs were being banned.

Whose responsibility is it to inform the public that Chloramphenicol, while justified in typhoid, when used for trivial infections especially in childhood diarrhoeas, (most of which are viral) can prove hazardous? Even if efficacious, the safety factor is low to justify its use for trivial indications. It can cause bone marrow depression, agranulocytosis, (i.e. fall in white blood cell count) and even death with resultant infection due to decreased resistance.

Salmonella (ie. micro organisms which cause typhoid) have in many places developed resistance to chloramphenicol, due to its misuse for indications where it is not rationally justified. Moreover the main treatment of

diarrhoea (i.e. Oral rehydration is marginalised and such drugs masquerading as diarrhoea treatment add further hazard.)

Where streptomycin in combination is concerned- when single ingredient streptomycin for TB patients is not available, its misuse in combination, (when safer and more effective alternatives exist) is not justified.

Whose responsibility is it to ensure that this pattern of obtaining Stay Orders routinely, even when potentially hazardous drugs are involved, are not granted?

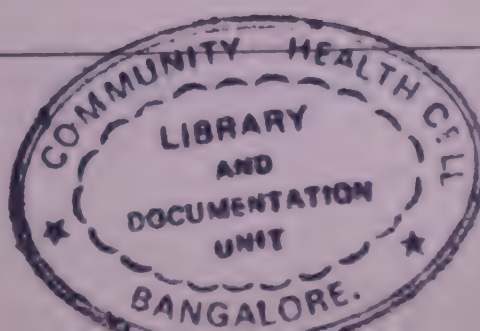
Whose responsibility is it to ensure that manufacturers who continue to challenge drug

control authorities and squeeze profits from the public are given deterrent punishment? In view of the failure of the Drugs and Cosmetics Act of 1940 and its amendment in 1982, and the Consumer Protection Bill of 1986 to protect the consumer, so far it is obvious that other measures need to be sought, besides making these acts more functional so as to safeguard the interest of the public.

In view of death or disability due to consumption of a banned drug who should be held accountable? The prescriber, the dispenser, the distributor, or the manufacturer? What should be the liability of the authorities responsible for weeding out irrational & hazardous drugs?

DR-410
N96

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THE GAZETTE OF INDIA

EXTRAORDINARY

PART II - SECTION 3 - Sub-Section (i)

PUBLISHED BY AUTHORITY

NO.575 NEW DELHI, THURSDAY, NOVEMBER 3, 1988/KARTIKA 12, 1910

MINISTRY OF HEALTH AND FAMILY WELFARE

New Delhi, the 3rd November, 1988

NOTIFICATION

G.S.R. 1057 (E), - Whereas the Central Government is now satisfied that long term use of steroids in fixed dose combination drugs for treatment of asthma is likely to involve risk to human beings and such formulations do not have therapeutic justification:

And whereas the Central Government is now also satisfied that fixed dose combinations of chloramphenicol for internal use is likely to involve risk to human beings:

And, whereas the Central Government is satisfied that it is necessary and expedient in public interest to prohibit the manufacture and sale of the drugs aforesaid.

Now, therefore, in exercise of powers conferred by section 26A of the Drugs & Cosmetics Act, 1940 (234 of 1940) the Central Government hereby makes the following further amendments in the notification of the Government of India, in the Ministry of Health and Family Welfare No.G.S.R. 578(E), dated 23rd of July, 1983 namely:-

In the Table under the said notification for items 14 and 15 the following items shall be substituted namely:-

“14. Fixed doses combination of corticosteroids with any other drug for internal use.

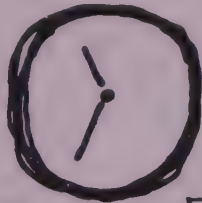
15. Fixed dose combinations to Chloramphenicol with any other drug for internal use.”

[No.X-11014/2/88-DMS & PFAJ
SMT. VINEETA RAI, Jt.Secy.

Note: Government of India Ministry of Health & Family Welfare Notification No.G.S.R. 578(E), dated 23rd July 1983 was amended by the following notification published in the Gazette of India, Extraordinary, Part II, Section 3(i) namely:-

1. G.S.R. 49(E) dated 31.1.1984.
2. G.S.R. 322 (E), dated 3.5.1984.
3. G.S.R. 8634(E), dated 22.11.1985.
4. G.S.R. 700 (E), dated 15.6.1988.

THIS SHOP SELLS ONLY
ESSENTIAL & RATIONAL DRUGS
BASED ON RECOMMENDATIONS
OF NATIONAL FORMULARY OF INDIA
AND W.H.O.



ANTIBIOTICS

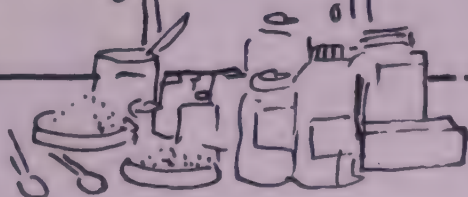
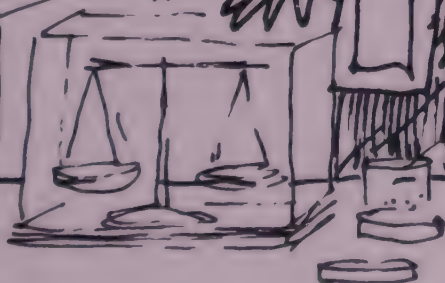
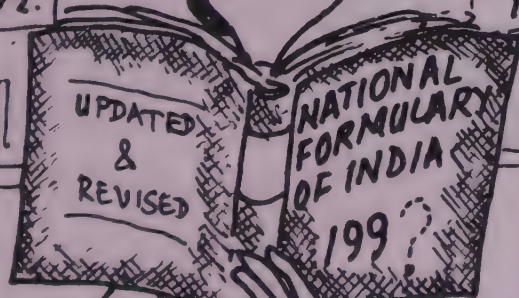
ANTIHELMINTHICS

ANTI HYPERTENSIVES

ANALGESICS

ANTI-EPILEPTICS

ANTI-ASTHMATICS



Stephen

ESSENTIAL DRUGS

(Taken from WHO's Technical Report Series No.825, 1992)

A. Criteria for the Selection of Essential Drugs

Essential drugs are those that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in the appropriate dosage forms.

The choice of such drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources; and genetic, demographic and environmental factors.

Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from clinical studies and for which evidence of performance in general use in a variety of medical settings has been

obtained.

Each selected drug must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established.

Where two or more drugs appear to be similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability.

In cost comparisons between drugs, the cost of the total treatment, and not only the unit cost of the drug, must be considered. The cost/benefit ratio is a major consideration in the choice of some drugs for the list. In some cases the choice may also be influenced by other factors, such as comparative pharmacokinetic properties, or by local considerations such as

the availability of facilities for manufacture or storage.

Most essential drugs should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has a proven advantage over single compounds administered separately in therapeutic effect, safety or compliance.

GUIDELINES FOR ESTABLISHING A LIST OF ESSENTIAL DRUGS

Since the first report on the selection of essential drugs was published in 1977, the concept of essential drugs has been widely applied. It has provided a rational basis not only for drug procurement at national level but also for establishing drug requirements at various levels within the health care system. In fact, many developing countries have already selected essential drugs according to their needs and the related programmes are, in some cases, at an advanced stage of implementation.

In order to ensure that an essential drugs programme is adequately instituted at national level, several steps are recommended:

1. The establishment of a **list of essential drugs**, based on the recommendations of a committee, is the starting-point of the programme. The committee should include individuals competent in the fields of medicine, pharmacology and pharmacy, as well as peripheral health workers. Where individuals with adequate training are not available within the country, cooperation from WHO could be sought.

2. **The international nonproprietary (generic) names** for drugs or pharmaceutical substances (11) should be used whenever available, and prescribers should be provided with a cross-index of non-proprietary and proprietary names.

3. **Concise, accurate and comprehensive drug information** should be prepared to accompany the list of essential drugs.

4. **Quality**, including drug content, stability and bioavailability, should be assured through testing or regulation, as discussed in section 5. Where national resources are not available for this type of control, the suppliers should provide documentation of the product's compliance with the required specifications.

5. Competent health authorities should decide the **level of expertise required to prescribe individual drugs** or a group of drugs in a therapeutic category. Consideration should be given, in particular, to the competence of the personnel to make a correct diagnosis. In some instances, while individuals with advanced training are necessary to prescribe initial therapy, individuals with less training could be responsible for maintenance therapy.

6. The success of the entire essential drugs programme is dependent upon the **efficient administration of supply**, storage and distribution at every point from the manufacturer to the end-user. Government intervention may be necessary to ensure the availability of some drugs in the formulations listed and special arrangements may need to be instituted for the storage and distribution of drugs that have a short shelf-life or require refrigeration.

7. **Efficient management of stocks** is necessary to eliminate waste and to ensure continuity of supplies. Procurement policy should be based upon detailed records of turnover. In some instances, drug utilization studies may contribute to a better understanding of the requirements.

8. **Research**, both clinical and pharmaceutical, is sometimes required to settle the choice of a particular drug product under local conditions. Facilities for such research must be provided.

9. A **national drug regulatory authority** should be established along the lines recommended in the guiding principles for small national drug regulatory authorities presented in Annex 1. The authority should interact with other interested bodies, including organizations responsible for drug procurement in the public and private sectors and the committee referred to in item 1.

B. ADVANTAGES OF THE CONCEPT OF ESSENTIAL DRUGS

Preparing a rational list of essential/restricted drugs has several advantages: medical, economic, social and administrative.

MEDICAL ADVANTAGES

- It is medically, therapeutically and scientifically sound, and it ensures rational use of drugs.
- It limits the use of irrational and hazardous drugs and decreases the risks of iatrogenesis.

- It improves the possibility of monitoring adverse drug reactions in patients.

ECONOMIC ADVANTAGES

- It is economically beneficial to the nation because it prevents wastage of scarce resources on non-essentials.
- The economics of scale achieved in the large production of priority drugs brings down their prices.
- It curtails the aggressive marketing of non-essential formulations.
- It is economically beneficial to the patient because it prevents wastage on irrational drugs and non-essentials.

SOCIAL ADVANTAGES

- It responds to the real health needs of the people.
- It facilitates the dissemination of correct information about the drugs to health personnel, medical practitioners and consumers in general.
- It makes it imperative to draw up priorities to meet the most urgent needs of the people for essential health care.

ADMINISTRATIVE ADVANTAGES

- It is organizationally sound because it makes quality control easier because of the limited number of drugs to be monitored.
- It facilitates the streamlining of production, storage and distribution of drugs, because of the smaller number of drugs involved.

- It helps in clear identification of the drugs,
- It facilitates the fixing of prices as well as the revision/withdrawal of excise duties, sales tax etc.

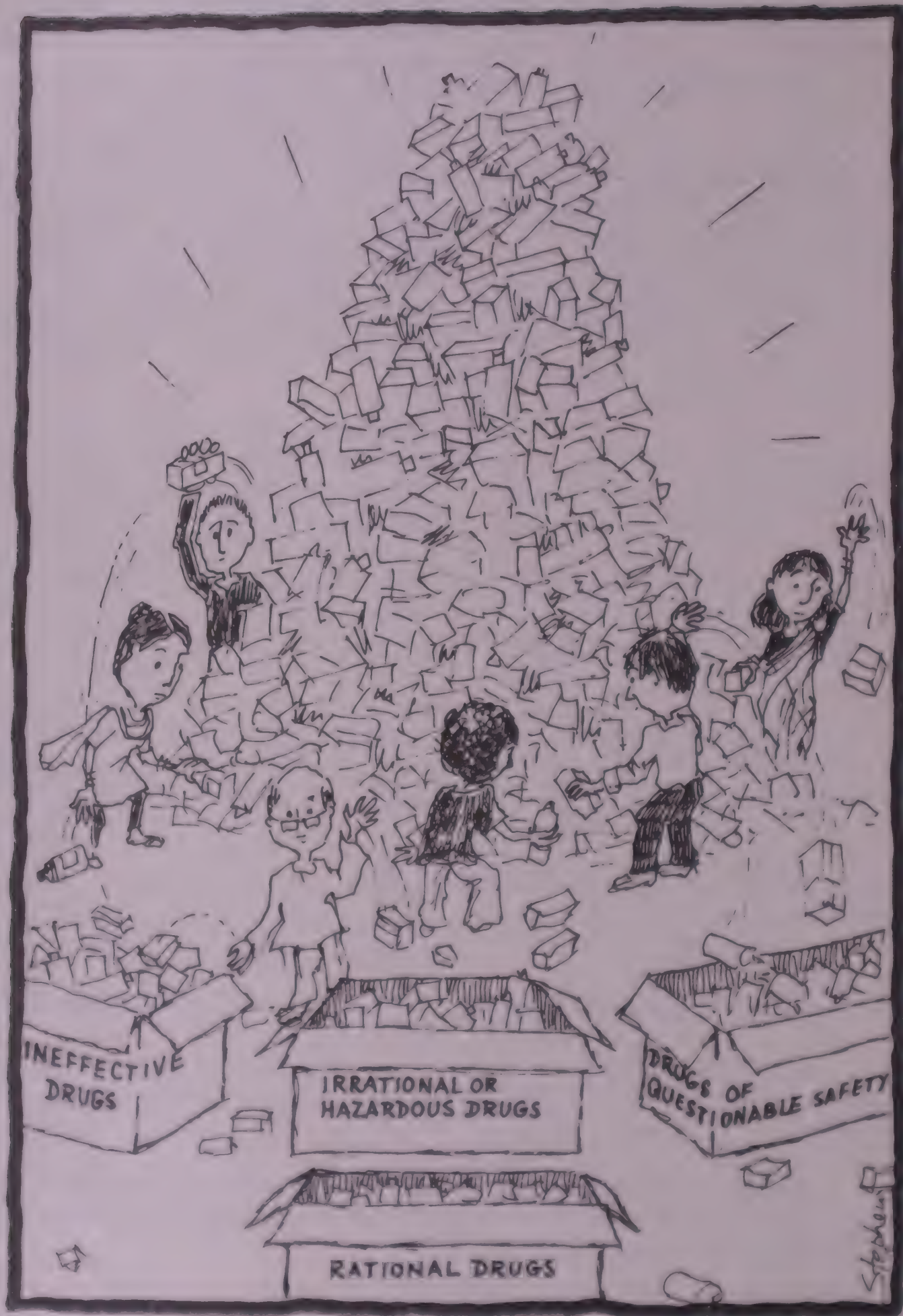
Inspite of the New Drug Policy of 1986 and its modifications 1995, we still do not have an Essential Drug list for the country.

Even if a list of category I & II drugs have been formulated; Category I — Drugs for

National Health Program, Category II — Other Essential Drugs, these drug lists had more to do with price fixation than with ensuring adequate productions of Essential Drugs.

International Consultation on Rational Selection of Drugs 1986 was organised by VHAI to influence the New Drug Policy towards making of Essential Drug Tests, Essential Drug Policy so far Delhi Govt. and Tamil Nadu state government have formulated Essential Drug Tests for their institutions in the public sector.¹

1. Rational Selection of Drugs, VHAI, 1986



BANGLADESH DRUG POLICY

BANGLADESH DRUG POLICY

The Bangladesh Drug Policy of 1982 was aimed at:

1. ensuring production of essential and life saving drugs,
2. withdrawal of irrational and hazardous drugs,
3. ensuring quality control,
4. national saving by limiting imports to only essential and priority drugs,
5. ensuring affordability of the drugs by curtailing price increase.

Major recommendations of the National Drug Policy.

The National Drug Policy of Bangladesh was seen as an integral part of the National Health

Policy - applicable not just for the **modern medical system** but also the **traditional system**, not just for the **public sector** but also the **private sector**.

The objective of the National Drug Policy was to rationalize procurement, production, quality control, distribution and drug pricing and bring it under a single legislative and administrative control. (Unlike in our country where loopholes between jurisdiction and accountability of drug policy matters between centre, state, Chemicals Ministry, Health Ministry and Commerce Ministry have never allowed rationalization of drug policy and seen repeated attempts sabotaged).

CRITERIA FOR WITHDRAWAL OF IRRATIONAL & HAZARDOUS DRUGS.

The sixteen criteria Bangladesh used in 1982 to decide which drugs were useful and which should be banned:

1. The combination of an antibiotic with another antibiotic or antibiotics with corticosteroids or

To ensure Rational Drug Use, there must be a rational drug policy. Bangladesh drug policy is a courageous example of such a policy.

other active substances will be prohibited. Antibiotics harmful to children (e.g. Tetracycline) will not be allowed to be manufactured in liquid form.

2. The combination of analgesics in any form is not allowed as there is no therapeutic advantage and it only increases toxicity, especially in the case of kidney damage. The combination of analgesics with iron, vitamins or alcohol is also not allowed.
3. The use of codeine in any combination form is not allowed as it causes addiction.
4. In general no combination of drugs will be

used unless there is absolutely no alternative single drug available for treatment or if no alternative single drug is cost effective for the purpose.

- Certain exceptions will be made in cases of eye, skin, respiratory and hemorrhoidal preparations, cotrimoxazole, oral rehydration salts, antimalarial, iron-folic, etc. as well as certain vitamin preparations, allowing combinations of more than one (1) active ingredient in a product.
5. Vitamins should be prepared as single ingredient products with the exception of B

BANNING OF DRUGS IN BANGLADESH

Finally, the drugs that were on the market were checked against the Guidelines resulting in a recommendation that 1,707 of them be withdrawn completely. The drugs to be banned were divided into three categories:

SCHEDULE ONE DRUGS: Regarded as harmful, these were to be forbidden from being made or imported **immediately** and withdrawn from sale within 3 month. The time delay was simply to collect and destroy the dangerous products.

Number affected: 305

SCHEDULE TWO DRUGS: These were medicines composed of combinations of similar or incompatible ingredients, which did not enhance their therapeutic value and which carried the risk of increased toxicity as well as being deemed unnecessarily expensive. **Six months** were allowed for selling off existing stock and submitting new formulations.

Number affected: 134

SCHEDULE THREE DRUGS : These were either considered useless and unnecessary or were famous brand name products made under license. No royalties were to be paid overseas any more for the right to use such a name patented abroad. Any pharmaceutical company based in Bangladesh could make a similar drug without

paying a license fee. All Schedule Three drugs were to be withdrawn within **nine months**.

Number affected: 1,268

Finally a list of drugs was drawn up by generic name for each level of the health system in the country. 12 essential drugs were for use in the village, an additional 33 for primary health care up to local health complex level (the small regional or town hospital) and a complete list of 150 drugs for use in the regional and national hospitals. A supplementary list of 100 drugs was established for restricted use by specialists.

The Drug Control (Ordinance) was implemented on 12th June 1982, effectively putting into law the Expert Committee's recommendations, although prolonging the time allowed for implementation of the three schedules to six, nine and eighteen months respectively. A later review committee brought in amendments which reduced the banned list of drugs by 60. Despite subsequent internal and international pressure, General Ershad and his government stood firmly behind the new policy. The substance of the original recommendations continues to form the basis of the National Drug Policy of Bangladesh. It came into full operation in June 1984.

complex. Vitamins will not be allowed to be combined with any other ingredient such as minerals, glycerophosphate, etc. It will be allowed to produce vitamins in tablets, capsules and injectable form only. No liquid forms will be permitted because of wastage of financial resources and the tremendous misuse involved. However, paediatric liquid multivitamin will be allowed to be manufactured in bottles of upto 15 ml. size with droppers. Paediatric liquid preparations of single ingredient vitamins will also be allowed to be manufactured in bottles of up to 15 ml. with droppers.

6. No cough mixtures, throat lozenges, gripe water, alkalis, etc will be allowed to be manufactured or imported as these are of little therapeutic value and amount to great wastage of our meagre resources.
7. The sale of tonics, enzymes, mixtures/preparations and so-called restorative products flourish on consumer ignorance. Most are habit-forming and with the exception of pancreatin and lactase, these are of no therapeutic value. Henceforth, local manufacture or importation of such products will be discontinued. However, pancreatin and lactase will be allowed to be manufactured and/or imported as single ingredient products.
8. Some drugs are being manufactured with only a slight difference in composition from another product but having similar action. This only confuses both patients and doctors. This will not be allowed.
9. Products of doubtful, little or no therapeutic value and rather sometimes harmful, and subject to misuse will be banned.
10. All prescription chemicals and galenical preparations not included in the latest edition of British Pharmacopoeia or British Pharmaceutical Codex, will be prohibited.
11. Certain drugs, in spite of known serious side effects and possibility of misuse, having

favourable risk-benefit ratio may be allowed to be produced in limited quantity for restricted use. These will be prescribed by specialists only.

12. The same or close substitute of a drug which is being produced in the country will not be allowed to be imported as a measure of protection for the local industry. However, if local production is far short of needs, this condition may be relaxed in some individual cases.
 13. A basic pharmaceutical raw material which is locally manufactured will be given protection by disallowing itself or its substitution to be imported unless sufficient quantity is not available in the country.
 14. The role of multinationals in providing medicines for this country is acknowledged with appreciation. In view of the calibre of machinery and technical knowhow which lies in their hands for producing important and innovative drugs for the country, the task of producing antacids and vitamins will be solely with the national companies, leaving multinationals free to concentrate their effort and resources on those items not so easily produced by smaller national companies. Multinationals will, however, be allowed to produce injectable vitamins in single ingredient products.
 15. No foreign brands will be allowed to be manufactured under licence in any factory in Bangladesh if the same or similar products are available or manufactured in Bangladesh, as this leads to unnecessary high prices and payments should be reviewed.
 16. No multinational company without their own factory in Bangladesh will be allowed to market their products after manufacturing them in another factory in Bangladesh on toll basis.
- After approval of these recommendations by Government, the licensing authority for drugs

(Director, Drug Administration) will have to issue necessary orders withdrawing/cancelling the licensing/registration of the products, with the provision of a maximum period of six months grace for using up the present stock of corresponding raw materials. Henceforth no raw materials should be allowed to be imported for the manufacture of these products. All future licensing/registration should be given after evaluation of the products on the basis of the above criteria.

Withdrawal of irrational and hazardous drugs cannot effectively take place in isolation, it has to be done in context of a Rational Drug Policy. Withdrawal of irrational and hazardous drugs and availability of essential and life saving drugs are flip sides of the same coin.

BANGLADESH

1. A basic essential drug list of 150 drugs established with 100 specialized drugs in the supplementary list.

150 drugs for tertiary care

45 drugs for primary health care

12 drugs for village health workers

2. Use of generic names for manufacture and sale of the 45 primary care drugs.

3. Preparation and Publication of National Drug Formulary.

4. Eliminate product patents and limit use of process patents.

5. Revise 1940 Drugs Act to include a registration system for Ayurvedic, Unani and Homeopathic medicines.

6. Enforcement of good manufacturing practices (GMP) including adequate quality control.

7. Control of labelling and advertising

8. Price Control

9. Prescription control of toxic poisonous

and habit forming drugs

10. Establishment of special drug courts and heavy penalties.

11. Regulation of technology transfer and licensing agreements with foreign collaborators.

12. Restriction of ownership of retail pharmacies to professional pharmacists only.

13. Set up a National Drug Control Lab by 1995.

14. Prevent TNC's from manufacturing simple products like common analgesics, vitamins, antacids

15. Establish registered retail pharmacies, under the supervision of qualified pharmacists, at every government hospital. Strengthen the Drug Administration by Training all Thana health administrators to act as drug inspectors.

In 1988 the National Health Policy which included integration of Health and Family Welfare decentralization of health program to (Upazila) Block

- introduction of medical audit and registration of all health workers.

- abolition of private practice for all teachers in government medical colleges and post graduate institutes and doctors upto the level of junior consultants.

- introduction of laws to ensure quality health care and compensation to persons who have suffered as a result of negligence by the medical profession.

- introduction of various other legislative and administrative measure.

The above National Health Policy which was formulated in the interest of the Bangladesh's public could have been sabotaged with the Bangladesh Medical Association going on 72 hour strike, expulsion of 3 of the doctors involved in formulating this progressive Health Policy. One of the formulators being Dr. Zafrullah Chowdhury the Chief Architect of the Bangladesh Drug Policy, recipient of the Magasaysay Award.

IMPACT OF THE DRUG POLICY

10 years after the National Drug Policy of Bangladesh is in place results show that not merely the country but its people have also benefited.

The achievements are as follows:

1. Increased production of Essential Drugs:

Essential Drug Production increased from 30% to 80% of total production 116 were identified as essential.

2. Removal of irrational and hazardous drugs: Over 1707 combination have been withdrawn.

While efforts towards getting irrational and hazardous drugs continue, our aim is improved health status and affordable rational health care services for our people specially the vulnerable and the marginalized which is not possible without implementations of rational drug and rational health policy.

It is in this context that the Bangladesh experience becomes important.

3. Affordability of Drugs: Decrease in Drug Prices

Drug price share decreased in a longer number of cases but if increased the increase has been marginal and the drug prices have statutized increasing only 20% as compared to 179% in the consumer price index.

4. National Saving with Import Substitution: Over \$ 600 million dollar saving has taken place with abolition of transfer pricing, decreased dependency on imports and prioritization of imports to essential drugs.

5. Increased local production: Share of local production increased from 35 to 60% with overall production increasing by 217%.

6. Quality Assurance: Improvement in quality control resulted in proportion of substandard drugs decreasing from 36% to 91%.

7. Rationalization of Prescription: A rational drug policy is crucial in rationalizing drug prescription.

A study conducted in 1992 by International network for Rational Use of Drugs with Pharmacology and Community Medicine departments of 4 medical colleges assessed drug use pattern for six common diseases.

The study found:

- average number of drugs per prescription was - 1.4%

- patients receiving drugs according to the prescriptions with adequate drug information was - 81%

- drugs selected from essential drug list-85%

- prescription by generic names - 78%

- patients treated with antibiotics - 24.5%

In 1990 8th anniversary of National Drug Policy prescription of misused therapeutic groups of drugs eg. antibiotics, narcotics, hormones (except contraceptives) was found to have decreased substantially.

INDIA

NO NATIONAL ESSENTIAL DRUG LIST

Attempts have been made by states eg. Delhi State, Tamil Nadu to formulate Essential Drug List, but these are ONLY for the public sector health institutions.

Since 80% of the drug usage is in private sector formulation and implementation of an Essential Drug list concept, unless it is for private

Ref: Politics of Essential Drugs, the Makings of a successful Health Strategy. Lessons from Bangladesh by Dr.Zafrullah Chowdhuy, Zed Books. London Oct.1995 SAGE PUBLISHERS Jan 1996
Development Dialogue - Making National Drug Policies a Development Priority - 1995
Pills Policies and Profits, Francis Rolt War on Want 1983
"Four years on" IOCU Andy Chetly 1987

as well as public sector, its effectiveness is limited.

Last national drug formulary was prepared in 1979. Neither the 1986 nor the 1994 New Drug Policies ensured its revision.

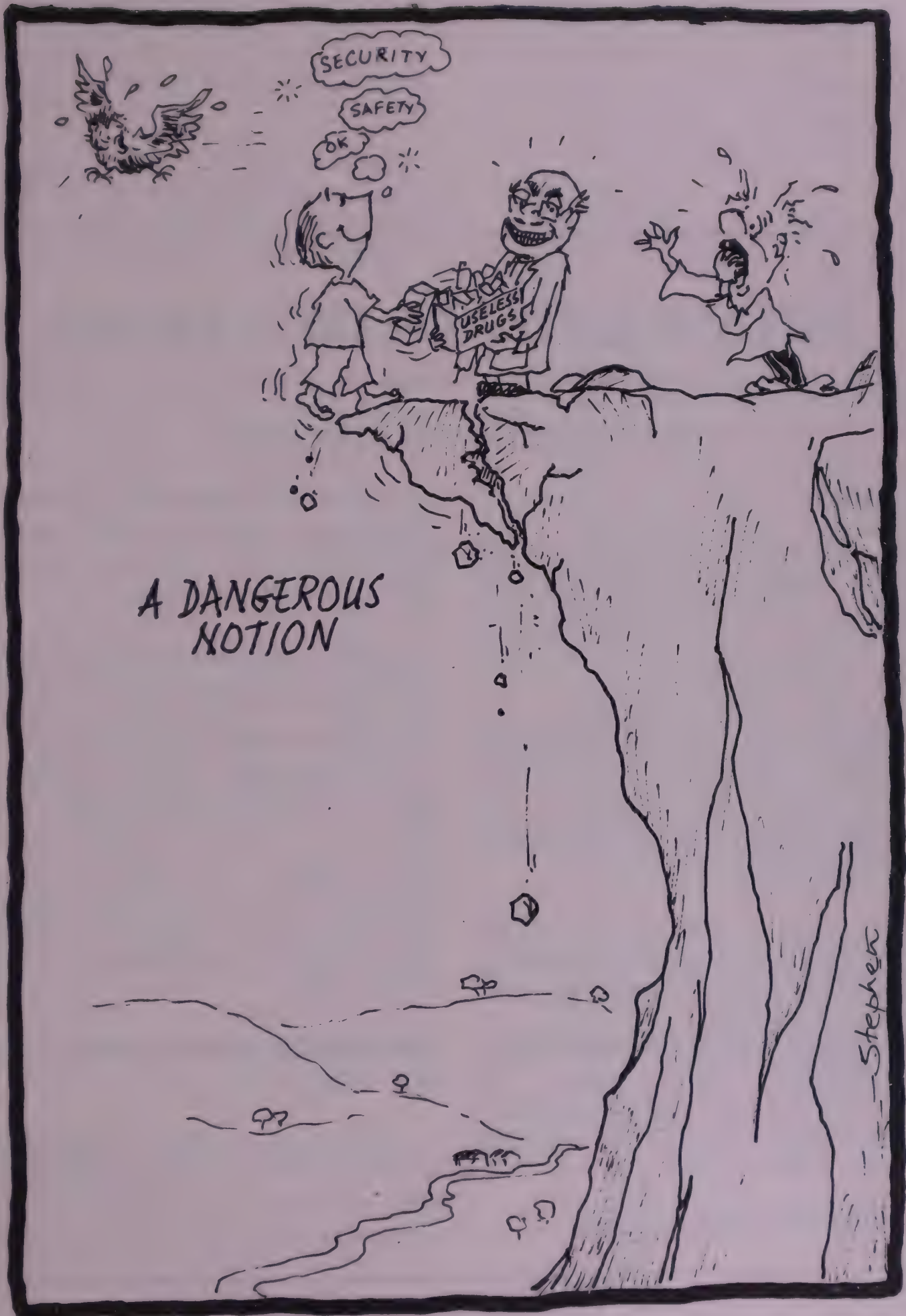
India's prestigious Patent Act of 1970 is under the threat of being destroyed under multilateral & bilateral pressures from Western countries in the form of TRIPS & Super 301.

When multilateral treaties have been signed, i.e. WTO, and which give time to India to change its patent act, bilateral pressure and threat of trade sanctions is unwarranted. It is a challenge to national sovereignty and nation's right to have regulations and laws in the interest of the nation and its people.

Armtwisting of Third world countries like India by the Governments of the western corporations, to take decisions against their own people is unethical, undemocratic and violation of human rights of the citizens.

It is good to remember that when under Presidentship of Dr. Allende of Chile a pro people drug policy was constituted, amongst the first people to be assassinated with him were the doctors involved in formulation of that drug policy.

As long as freedom to profiteer will be seen as the goal, the price that will be paid will be in "public health". Regulation of the global and national Trade in drugs is crucial for public health.



DRUGS AND LEGISLATIONS

THE CONSTITUTION OF INDIA

PREAMBLE

WE, THE PEOPLE OF INDIA HAVING SOLEMNLY RESOLVED TO CONSTITUTE INDIA INTO A SOVEREIGN SOCIALIST SECULAR DEMOCRATIC REPUBLIC AND TO ALL ITS CITIZENS.

JUSTICE, SOCIAL, ECONOMIC AND POLITICAL, LIBERTY OF THOUGHT, EXPRESSION, BELIEF, FAITH AND WORKSHIP: EQUALITY OF STATUS AND OF OPPORTUNITY AND TO PROMOTE AMONG THEM ALL.

FRATERNITY ASSURING THE DIGNITY OF THE INDIVIDUAL AND THE UNITY AND INTEGRITY OF THE NATION.

IN OUR CONSTITUENT ASSEMBLY THIS TWENTY SIXTH DAY OF NOVEMBER 1949 DO HEREBY ADOPT, ENACT AND GIVE TO OURSELVES THIS CONSTITUTION.

CONSTITUTION OF INDIA

DUTY OF THE STATE TO RAISE THE LEVEL OF NUTRITION AND THE STANDARD OF LIVING AND TO IMPROVE PUBLIC HEALTH.

THE STATE SHALL REGARD THE RAISING OF THE LEVEL OF NUTRITION AND THE STANDARD OF LIVING OF ITS PEOPLE AND THE IMPROVEMENT OF PUBLIC HEALTH AS AMONG ITS PRIMARY DUTIES AND IN PARTICULAR, THE STATE SHALL ENDEAVOUR TO BRING ABOUT PROHIBITION OF THE CONSUMPTION EXCEPT FOR MEDICAL PURPOSES OF INTOXICATING DRINKS AND OF DRUGS WHICH ARE INJURIOUS TO HEALTH.

THE DRUGS AND COSMETICS ACT 1940

The Drugs and Cosmetics act, 1940 and the Drugs and Cosmetics Act Amendment 1982, are the main drug legislations that are supposed to provide some form of control over

the manufacture and sales of drugs.

The Drug Controller of India has the powers to prohibit manufacture of drugs which are not in public interest.

26A. POWER OF CENTRAL GOVERNMENT TO PROHIBIT MANUFACTURE ETC. OF DRUG AND COSMETIC IN PUBLIC INTEREST.

Without prejudice to any other provision contained in this chapter if the central government is satisfied, that the use of any drug or cosmetics is likely to involve any risk to human beings or animals, or that any drug does not have the therapeutic value claimed, or purported to be claimed for it or contained ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then the government may, by notification in the official gazette prohibit the manufacture, sale and distribution of such drug or cosmetic.

28B. PENALTY FOR MANUFACTURE ETC. OF DRUGS OR COSMETICS IN CONTRAVENTION OF SECTION 26A.

Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetics in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to 3 years and shall also be liable to fine which may extend to Rs.5000.

30. PENALTY FOR SUBSEQUENT OFFENCES

1. Whoever having been convinced of an

offence:

- (a) Under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 6 years and with fine which shall not be less than Rs.10,000. Provided that the court, may for any judgement impose a sentence of imprisonment for a term of less than 2 years and of fine of less than Rs.10,000.
- (b) Under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 6 years but which may extend to 10 years and with fine which shall not be less than Rs.10,000.
- (c) Under clause (d) of section 27 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than 2 years but which may extend to 4 years or with fine which shall not be less than Rs.5000 or with both.
- (d) Under clause (b) of section 27 is again convicted of an offence under that clause shall be punishable with imprisonment for a term which may extend to 10 years or with fine or with both.

31. CONFISCATION

32. COGNIZANCE OF OFFENCES

No prosecution under this chapter shall be instituted except by an inspector.

33. POWER OF CENTRAL GOVERNMENT TO MAKE RULES

POWER TO GIVE DIRECTIONS.

The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule made there under.

- (1) The Central Government may after consultation with, or on the recommendation of the Board and after previous publication by notification in the official gazette make rules for the purpose of giving effect to the provision of the chapter.

COMMENTS ON SECTION 33E

The Act of possessing a contraband or a prohibited article constitutes a continuing offence. A dealer could not possess such drugs during any period following the date of the issue of Notification and there after (Subhash Chander VS State of Punjab and others AIR 1989 P and H 238).

COMMENT ON SECTION 239

If a dealer is found selling, stocking or exhibiting for sale the prohibited drugs, an Inspector appointed under this Section can prosecute him by filing a complaint to the court who may in turn punish him (Subash Chander VS State of Punjab and others, AIR 1979 P and H 238).

THE CONSUMER PROTECTION ACT, 1986

Objectives of the ACT:

The Consumer Protection Act, 1986(68 of 1986) is a milestone in the history of socio-economic legislation in the country. It is one of the most progressive and comprehensive piece of legislation enacted for the protection of consumers. The new law has been enacted after in-depth study of consumer protection laws and arrangements in the U.K., U.S.A., Australia and New Zealand. Before its formulation, consultations with representatives of consumers, trade and industry were held. Various ideas and suggestions were also considered in a number of inter-ministerial meetings within the Government.

The main objective of the new law is to provide for the better protection of the consumers. Unlike existing laws which are punitive or preventive in nature, the provisions of this ACT are compensatory in nature. The Act intends to provide simple speedy and extensive redressal to the consumer's grievances. For this purpose the Act envisages a three-tier quasi-judicial machinery at the national, state and district levels. The Act enshrines certain rights of the consumers and provides for the setting up of Consumer Protection Councils in the centre and the states. The objective of these Consumer Protection Councils will be to promote and protect the rights of the consumers.

Extent and Coverage of the Act:

The salient features of the Act are summed up as under:-

- The Act applies to all goods and services unless specifically exempted by the Central Government.
- It covers all the sectors whether private, public or cooperative.
- The provisions of the Act are compensatory in nature.
- It enshrines the following rights of the consumers.:
 - (i) the right to be protected against the marketing of goods which are hazardous to life and property.
 - (ii) the right to be informed about the quality, quantity, potency, purity, standard and price of goods so as to protect the consumer against unfair trade practices.
 - (iii) the right to be assured, wherever possible, access to a variety of goods at competitive prices;
 - (iv) the right to be heard and to be assured that consumers' interests will receive due consideration at appropriate forums;
 - (v) the right to seek redressal against unfair trade practices or unscrupulous exploitation of consumers; and
 - (vi) the right to consumer education.
- The Act envisages establishment of Consumer Protection Councils at the central and state levels whose main object will be to promote and protect the rights of the consumers.
- To provide simple, speedy and inexpensive redressal of consumer grievances, the Act envisages a three-tier quasi-judicial machinery at the national, state and district levels. At the national level, there will be a National Consumer Disputes Redressal Commission (to be known as the 'National Commission'). At the state level, there will be Consumer Disputes Redressal Commissions (to be known as 'State Commission') and at the District level, there will be Consumer Disputes Redressal Forums (to be known as 'District Forums').
- The provisions of this Act are in addition to and not in derogation of the provision of any other law for the time being in force.

Who is a consumer?

All of us are consumers of goods and services. The producers of some goods and services also consume various other goods and services produced by others. In the Consumer Protection Act, the word 'Consumer' has been defined separately for the purpose of goods and services.

- For the purpose of goods, a consumer means a person belonging to the following categories:
 - (i) One who buys any goods for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment;
 - (ii) It includes any user of such goods other than the person who actually buys goods and such use is made with the approval of the purchaser.

For the purpose of services, a consumer means a person belonging to the following categories:

- (i) One who hires any service or services for a consideration which has been paid or promised or partly paid and partly promised or under any system of deferred payment;
- (ii) It includes any beneficiary of such service other than the one who actually hires the service for consideration and such services are availed with the approval of such person.

Who can file a complaint?

Following categories of persons may file a complaint under the Act:

- A consumer.
- Any voluntary consumer organisation, registered under the Societies Registration Act 1860 or the Companies Act, 1956 or under any other law for the time being in force.
- The Central Government.
- The State Governments or Union Territory Administrations.

What constitutes a complaint?

Under the Act, a complaint means any allegation in writing made by a complainant in regard to one or more of the following:

- That he has suffered loss or damage as a result of any unfair trade practices adopted

by any trader.

- That the goods mentioned in the complaint suffer from one or more defects.
- That services mentioned in the complaint suffer from deficiencies in any respect.
- That a trader has charged for the goods mentioned in the complaint, a price in excess of the price
 - (i) fixed by or under any law for the time being in force; or
 - (ii) displayed on goods;
 - (iii) displayed on any packet containing such goods.
- The definition of 'goods', 'services' and 'unfair trade practices', 'defect' and 'deficiencies' are given in the Annexure-I.

Where to file a complaint?

- If the cost of the goods or services and compensation asked for, is less than rupees one lakh, then the complaint can be filed in the District Forum which has been notified by the State Government for the district where the cause of action has arisen or where the opposite party resides.
- If the cost of the goods or services and compensation asked for is more than rupees one lakh but less than rupees ten lakhs, the complaint can be filed before the State Commission notified by the State Government or the Union Territory concerned.
- If the cost of goods or services and

compensation asked for, exceeds rupees ten lakhs, the complaint can be filed before the National Commission at New Delhi.

How to file a complaint?

Procedures for filing complaints and seeking redressal are simple and speedy.

- There is no fee for filling a complaint before the District Forum, the State Commission or the National Commission.
- The complainant or his authorised agent can present the complaint in person.
- The complaint can be sent by post to the appropriate Forum/Commission.
- A complaint should contain the following information:
 - a) the name, description and the address of the complainant;
 - (b) the name, description and address of the opposity party or parties, as the case may be, as far as they can be ascertained;
 - (c) the facts relating to complaint and when and where it arose;
 - (d) documents, if any, in support of the allegations contained in the complaint;
 - (e) the relief which the complainant is seeking.
- The complaint should be signed by the complainant or his authorised agent.

Relief available to consumers:

Depending on the nature of relief sought by the consumer and facts, the Redressal Forums may give orders for one or more of the following reliefs:

- (a) removal of defects from the goods;
- (b) replacement of the goods;
- (c) refund of the price paid; or
- (d) award of compensation for the loss or injury suffered.

Procedure for filing the appeal:

- Appeal against the decision of a **District Forum** can be filed before the State Commission within a period of thirty days. Appeal against the decision of a **State Commission** can be filed before the National Commission within thirty days. Appeal against the orders of the **National Commission** can be filed before the **Supreme Court** within a period of thirty days.
- There is **no fee** for filing appeal before the State Commission or the National Commission.
- Procedure for filing the **appeal** is the same as that of complaint, except that the application should be accompanied by the orders of the District Forum/State Commission as the case may be and reasons for filing the appeal should be specified.

Time limit for deciding complaint/ appeal

The thrust of the Act is to provide simple, speedy and inexpensive redressal to consumer

grievances. To ensure speedy disposal of consumer grievances, the following provisions have been incorporated in the Act and the rules framed thereunder:

- It is obligatory on the complainant or their authorised agents and the opposite parties to appear before the Forum/Commission on the date of hearing or any other date to which hearing could be adjourned.
- The National Commission, State Commission and District Forums are required to decide complaints, as far as possible, within a period of three months from the date of notice received by the opposite party where complaint does not require analysis or testing of the commodities and within five months if it requires analysis or testing of commodities.
- The National Commission and State Commissions are required to decide the appeal, as far as possible, within 90 days from the first date of hearing.

Definitions

- (i) “goods” means goods as defined in the Sale of Goods Act, 1930 (3 of 1930).
- (ii) “service” means service of any description which is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, entertainment, amusement or the

purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service;

- (iii) the expression “unfair trade practice” shall have the same meaning as in section 36A of the Monopolies and Restrictive Trade Practices Act, 1969, but shall not include an unfair trade practice adopted by the owner of an undertaking to which Part A of Chapter III of that Act applies or by any person acting on behalf of, or for the benefit of, such owner.
- (iv) “defect” means any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force or as is claimed by the trader in any manner whatsoever in relation to any goods.
- (v) “deficiency” means any fault, imperfection, shortcoming or inadequacy in the quality, nature and manner of performance which is required to be maintained by or under any law for the time being in force or has been undertaken to be performed by a person in pursuance of a contract or otherwise in relation to any service.

DOS AND DON'TS - A CHECKLIST FOR DOCTORS AND PATIENTS

In our day to day life there are several situations when one could have avoided a mistake and saved the situation. To err is human' it is said but only to a certain extent

*Note medical service & doctors have been brought under CPA. though govt hospitals & others providing free services have been excluded.

whereafter other factors intervene and the errant gets the lesson in a bitter manner. Every profession has its own principles and one gets more and more refined and experienced with the passage of time and constant practice. Here, the intention is not to superimpose the view, pragmatic opinion and advice of the author on the prevailing profession practices which are more intricately in the knowledge of the people practising the noble profession but to help obviate some of the avoidable irregularities which ultimately lead to an inference of negligence on the part of the doctor.

Checklist for Doctors

- (1) Ordinary and reasonable care and skill should be applied at all times with all patients.
- (2) Detailed records in respect of all the patients should be methodically maintained.
- (3) Consent of the patient whenever the situation demands must be obtained in writing.
- (4) Laboratory tests should be carried out whenever it is necessary to corroborate and confirm the diagnosis.
- (5) X-Ray filming should be advised in case of suspected fracture of bones and other related diseases of the joints.
- (6) A specialist should preferably be consulted in case if diagnosis is not precise.
- (7) Before prescribing or injecting any drugs do ascertain whether the same would have any reaction adverse to the patient.
- (8) Administration of tetanus or such other immunisation should be carried where the situation so demands.
- (9) Do not go beyond the point of your skill.
- (10) Always ensure that the drug which is going to be administered or injected is properly identified and is not something different.
- (11) In case there is suspicion that the patient is suffering from cancer. AIDS or similar disease, adopt the proper procedure as is prescribed by the medical authorities concerned.
- (12) In cases of surgery, consent of the patient is to be taken beforehand.
- (13) A duly qualified Anaesthetist should look after the branch of anaesthesia after taking all possible precautions till the time of revival of the patient.
- (14) Administer antibiotics in cases needing them.
- (15) In case an operation is to sterilize either of the spouse consent of the couple should be obtained.
- (16) In case the nature of treatment is new or an experiment, consent of the patient should be obtained.
- (17) A patient who is undergoing labour should be attended to without any lapse.
- (18) Always give proper instructions regarding the dosage, duration, and likely effect of medicines to the patient.
- (19) Always give clearcut instructions for post-operative care and check up to the patients.
- (20) Do suggest appropriate treatments for

chronic patients.

(21) Do not allow at any cost infection of any kind to spread and cause damage to patients.

(22) Do not delegate that part of your duty which is within your professional competence and always keep constant supervision over juniors and assistants.

(23) Keep yourself informed about the latest developments in the various branches of the medical field.

(24) Advice immediate hospitalization in critical and terminal cases where first aid or your professional skill and facilities cannot cope with the emergency.

(25) In cases of medico-legal implications be prompt to inform the police but do take such steps as are warranted in the ordinary course to attend to a patient.

(26) Before administering anaesthesia the machine and the hose pipes should be properly checked and fitted.

(27) The clinics and hospitals should be kept clean and free from all sorts of infections.*

(28) Nursing homes claiming round-the-clock service should ensure competent doctors are available to look after ailing patients and to attend emergencies at all times.

(29) Never overstate your qualifications. (30) As a specialist more care is expected from you.

(31) Keep standard instruments and appliances duly sterilised.

(32) Have experienced nurses and sub-staff to attend the patients.

(33) Give complete details of fees charged from a patient.

(34) Remember, publicity is prohibited.

(35) Issue genuine certificates and bills.

(36) Always attend your patient when called.

(37) In case the patient has come from another doctor his previous treatment record should be taken.

(38) Give complete instructions/warnings about the manner in which a medicine is to be taken and possible side-effects.

(39) While dispensing your own medicines and before giving an injection be careful to read the packings and labels generally in cases of similar compounds.

(40) Do not hesitate to treat a patient for fear of the law. Every patient is not a potential litigant.

Checklist for Patients

(1) Always maintain your medical-history records.

(2) Always retain your prescriptions, bills and references.

*Ensure proper Treatment of Hospital waste

(3) Remember, your consent can be used as evidence in the court.

(4) Try to get first aid in case of emergencies on your own before medical help reaches you.

(5) Take prescribed doses of medicine.

(6) Observe post-operative instructions strictly.

(7) Do not let the ailment take its terminal course and then blame the doctor.

(8) Do not hesitate to donate blood.

(9) In case of doubts, second opinion is advisable.

(10) According to the nature of disease, one may go to a specialist.

(11) If hospitals are very crowded try to keep the patient under medical observation at home, if advisable.

(12) Remember, doctors are professional practitioners, not magicians.

(13) Do not panic in case of adverse reactions, it may demoralise your physician and prevent him from taking recovery step.

(14) Do help the medical staff in fulfilling the formalities in medico-legal cases.

(15) Do not hesitate to help a roadside victim in hit and run cases. It is your moral and legal obligation to do so.

(16) Every medical mishap cannot be attributed to negligence. Exaggeration may lead to selective and cautious treatment leading to more expense and risk.

(17) Purchase medicine as per prescription.

(18) It's your life!

Conflicts of Interest

Acting in the patient's best interests may conflict with the physician's self-interest or the interests of third parties such as insurers. The ethical ideal is to keep the patient's interest paramount. Otherwise physicians violate their fiduciary duty to patients and undermine trust in the profession.

Financial Incentives: In managed care systems, primary care physicians may serve as gatekeepers who authorize hospitalisations and referrals and who may be financially liable for expenditures. Such arrangements need to be disclosed to patients. The ethical concern is that physicians may withhold beneficial care in order to control costs. In contrast, physicians have incentives to provide more care than indicated when they receive fee for service reimbursement or when they refer patients to medical facilities in which they have invested. Regardless of financial incentives, physicians should recommend available care that is in the patient's best interest - no more and no less.

Gifts from pharmaceutical companies:

*Physicians often receive gifts ranging from pens and notepads to lavish entertainment.

Ref.:— Universal's Handbook Medical Negligence and Legal Remedies with Special Reference to Consumer Protection Act Pages 61 to 66.

Some people worry that any gift from drug companies may render physicians less objective. Physicians may underestimate the influence of commercial information on their patient care decisions. Even the appearance of bias and conflict of interest may be deleterious. In accepting gifts from drugs companies, physicians may contribute to higher drug prices that patients ultimately must pay.¹

GUIDE TO THE "THERAPEUTIC JUNGLE"

The flood of new drugs in recent years has provided many dramatic improvements in therapy, but it has also created a number of problems of equal magnitude. Not the least of these is the "therapeutic jungle", the term used to refer to the combination of the overwhelming

number of drugs, the confusion over nomenclature and the associated uncertainty of the status of many of these drugs. A reduction in the marketing of close congeners and drug mixtures, and an improvement in the quality of advertising are important ingredients in the remedy for the "therapeutic jungle". However, physician can also contribute to the remedy by employing non proprietary rather than proprietary names wherever appropriate, by using prototypes both as an instructional device and in clinical practice, by adopting a properly critical attitude toward new drugs, and by knowing and making use of reliable sources of pharmacological information. Most important, they should develop a "way of thinking about drugs", based upon pharmacological principles.²

1. Harrison's : Principles of International Medicine 13th edn. 1994 p.8

2. Goodman & Gilman's, The Pharmacological Basis of Therapeutics. 8th edn. 1991, P 78-79

The Lentin Commission Report

Some Implications

J.J. DEATHS, THE LENTIN COMMISSION REPORT —SOME IMPLICATIONS

“These pages describe and illustrate ugly facts of the human mind and human nature, projecting errors of judgement, misuse of ministerial power and authority, apathy towards human life, corruption nexus quid pro quo between unscrupulous, license holders, analytical laboratories, elements in Industries Department controlling the awarding of rate contracts, manufacturers, traders, merchants, suppliers, the FDA and persons holding ministerial rank.

None of this will be palatable in the affected quarters. But that cannot be helped.”

Thus starts the introduction of the Commission of Inquiry into the J.J. deaths headed by Honourable Mr. Justice Bakhtawar Lentin.

The Lentin Commission report is not a

report of 14 needless deaths, it is about the rot that has afflicted our health care system, because this noble profession is increasingly being controlled by men greedy for money and power.

The Story in Brief

Between 21st January and 7th February 1986, 14 patients died in J.J. Hospitals, they died of a cause totally unrelated to the treatments that brought them there. They died of toxicity or should we say poisoning by the adulterated glycerol given to them.

The toxic adulterant was Diethylene glycol which was present in the concentration of 18.5% as found later i.e. 3½ times the lethal dose, even 1% of Diethylene glycol is known to cause damage. These patients died of acute renal failure as rapid necrosis of the kidney tissue took place.

This adulterated glycerol meant for Industrial purpose was sold by the Kailash Co.

to Alpana Pharma with the former knowing that it was to be used for Medicinal purpose. This was not a mistake, nor an act of carelessness. It was an extremely conscious act motivated by greed for more profits.

Alpana Pharma which provided the glycerol to J.J. Hospital did not have its own manufacturing unit or drug testing lab.

Its tender to supply glycerol had been accepted by the Tender Committee in gross violation of the rules of acceptance of tender.

Mr. Ramanlal Karwa of Artichem Lab. on behalf of Alpana Pharma had paid Rs.18000 to Dr. R.D. Kulkarni the key person in the Tender Selection Committee to conduct bio-availability studies, which were actually not expected to have been conducted. The real reason for payment being the clearance of the tender. This tender was the 5th lowest, with obviously no advantage such as better quality control assurance. Lentin Commission states that "Dr. R.D. Kulkarni awarded the rate contract to Alpana Pharma for extraneous consideration".

Licensing authority

The issuing of licenses was in the hands of men found to be corrupt. The Deputy Drug Commissioner of Maharashtra Mr. S.M. Dolas enjoyed great powers, even more than the Drug Commissioner. He managed to supersede his seniors and spend 20 years out of 28 years of his official career posted in Bombay when transfers are ordered after every 3 years. Any attempt at posting him out was thwarted. He was protected by previous and present health ministers whom he obliged in return.

He had a departmental enquiry against

him on charges of negligence, inefficiency, maladministration, dereliction of duty.

Drug Testing Laboratory

Chem Med which gave the clearance to this industrial glycerol of being of standard quality, did not conduct the required tests. Had it not been for Chem Med's certifying of glycerol to be of standard quality it would not have been supplied to J.J. Hospital. The Commission noted that "Chem Med was found guilty several times of gross irregularities in matter of analysis of drugs and or issuance of Test Reports without actually carrying out the tests and had accepted and suffered the punishments in respect thereof". It is obvious that this had happened not for the first time, it was a pattern.

Tender Committee

The key person in the Tender Committee was Dr. R.D. Kulkarni, Prof. and Head of Pharmacology Department of J.J. Hospital, Dr. R.D. Kulkarni had not only accepted Rs.18000/- from Alpana Pharma, but had accepted Rs. 1 lakh from Hoechst and Rs.1.5 lakhs from Himalayan Drug House for his clinical research centre. The accounts of which he was free to operate, and these accounts were not taxed, but were put to personal use in repair of car, in building of house, and dry cleaner bills.

The inaction of the Highest authorities in J.J.

Even while the patients started dying and the culprit drug was more or less identified, the toxic glycerol continued to be given in Ophthalmology Department as anti-oedema

agent. This continued usage and nonwithdrawal of the drug continued for a few more days?

This was due to total inaction by the Dean, Dr.R.S., Chandrikapure and the Medical Supt. and Dr.V.G.Deshmukh, even when they were informed. The letter requesting urgent actions by the nephrology department sent through their ward boy was returned unsigned because the latter had not brought a pen to sign it with, and Dr.Deshmukh was going out shopping.

About these 2 luminaries Justice Lentin has the following to say "The captain and his lieutenant failed in their duties and abdicated their responsibilities and abandoned the ship in the hours of crisis. These two were as negligent, inefficient, brutal, cynical and lazy in doing their duty, as their incalculable for shrugging off responsibility, knowing neither thought nor remorse. They are unfit to hold any post involving responsibility".

The Pharmacology Department

The Clinical Pharmacologist Dr. S.V. Shaligram rather than immediately withdrawing the toxic drug in question was more interested in conducting animal studies to identify the toxic drug. To him Justice Lentin said during the proceedings "You seemed to have reached for the moon and ignored the sick men at your feet".

About Health Ministers

Justice Lentin states that "they have encouraged corruption, favouritism, deliberate violation of the Act and Rules by their own acts of omission and commission, intentionally and knowingly performed with a view to confer

favours or ministerial largesse in the form of transfers and posting of choice, undeserved promotions of FDA officers and concessions, cancellations, of stringent orders or withdrawal or withholding of mandatory prosecution in accordance with the provision of the Act against the licenses viz. manufacturers and repackers etc."

Since a very large percentage of the drugs registered in the country are registered in Maharashtra - the way the drug industry and the FDA functions in Maharashtra definitely affects others.

Probably many more have died, and many more will die slowly. They will remain undiagnosed and uncompensated, in the absence of any systematic monitoring of adverse drug reaction even to known hazardous drugs.

The tragedy continued thereafter in another form. FDA officials incharge of investigating the tragedy tried to shield the guilty and give false reports. Even the contaminated bottles of adulterated glycerol were not seized by FDA. This was brought out by the Lentin Commission.

The Lentin Commission

The Lentin Commission was set up on orders from the Supreme Court to Maharashtra as a response to a letter to Justice Bhagwati by Dr.N.H.Antia about the need to investigate unbiasedly the J.J.Tragedy.

The Lentin Commission started its work on June 21st 1986 till 9th November 1987 and over 17 months worked over 301 hours. It examined 120 witnesses, recorded 3732 pages of evidence. It sat through all court vacations

working full days often on Saturday. The commission staff and the 5 stenographers worked day and night and in record breaking 3 weeks got the report ready by deadline of 30th nov.1987.

It was the 1st commission that sat through, took cognizance of those witnesses who failed to tell the truth in the witness box and slapped perjury notices against 4 persons including 2 former health ministers.

The commission continued its diligent functioning inspite of threat of stoppage of funds, and inspite of suppression of fact and files, "delving out details from recalcitrant and hostile witnesses".

The court proceedings and the report itself have looked deeply into the legal, medical, social, ethical issues - and the report makes rich reading not merely in terms of bringing to light little known horrifying facts brought out, but because of evidence of literary skills, wit and dountless courage.

The Lentin Commission's Terms of Reference and main recommendations are available with us.

Some of the statements made by Justice Lentin will go into the list of famous quotable quotes eg. about FDA.

During the proceeding Justice Lentin reacting in one situation stated that "asking FDA officers as to who signed is like asking a tiger why it eats sheep:."

On Page 139 of his report the Lentin Commission states about the FDA "The entire structure of FDA, at one time a prestigious

body famous in all Asia has been corroded by rampant and unabashed corruption, deleterious indiscipline, naked favouritism, crude nepotism and gross ministerial interference at every stage and a "Sense of non-accountability all around".

At one point utterly disgusted with the evasiveness of Mr.S.M. Dolas, Justice Lentin said "with the mental gymnastics of this witness I am sure he will become a commissioner and when the court sniggered, the judge added it is not a joke, it is prophecy."

Times of India aptly described FDA as "Friends of Drug Adulterators" Justice Lentin called the FDA "Father Dolas Administration".

Lentin advised a particularly brazen FDA official "Learn to keep alive in your breast the celestial fire called conscience. George Washington said that, have you heard of him?"

When asked as to what was unique about the commission Justice Lentin stated that never in his experience of 14 years in High Court bench and 7 years in the civil court had he come across any case where barring a few exceptions, witness after witness came determined to suppress the truth and piling the blame on subordinates.

The Lentin Commission Report cannot and should not be treated as the investigation report of 14 deaths in J J. Hospital, it is a report of the rot which has been allowed to set in high and low places and this rapidly deteriorating trend must be stopped before it is too late. Stopping this rot is health action.

An analysis of how much the Drug Acts have been used to bring the guilty parties to book shows that the act has been rarely

implemented and no real deterrent punishment given. The question today in assessment of the drug situation is not just knowing the production, export and import figures but of "who" is taking the decisions, "why" and at "who's costs". Till that is understood and interventions made accordingly it is unlikely that things will change. Those involved in corruption where health and lives of people are concerned need to be exposed and treated as criminals by society. Where drug controls and legislations fail moral and public pressure alone can shame them into repetition of such acts being prevented, along with stringent punishment of course, of the guilty as well as their protectors.

When most of the government official indicted by the Lentin Commission on the J J Hospital deaths scandal have been exonerated by the government. Mr. L.V. Raykar, Assistant Commissioner, FDA has had to bow out unceremoniously as he has been dismissed by the government. Mr. Raykar stated that the government acted very indictively against him because he assisted the Lentin Commission during its enquiry. Dr.R.S. Chandrikapure was reinstated as Dean of the government medical hospital, Nagpur and Dr.S.V. Shaligram as Professor of pharmacology at the Grant Medical College, Bombay. Justice Lentin had estimated that Dr. Hiray had collected about Rs.40 to 50 lakh in 1981. An independent enquiry by a retired judge, MD Kambli has

confirmed the Lentin Commission findings on how the former Maharashtra Health Minister Dr.Baliram Hiray lied his way to illgotten wealth. Report recommended that Hiray should not be appointed to any public office, elective or otherwise.

Lentin Commission recommended that drugs found to be substandard or spurious should be made public along with the names of the manufacturers and the batch numbers. This is being done.

Where indictment of the guilty is concerned the story has been similar to the dozens of cases filed against violaters of Drug & Cosmetics Act, or where commissions have held those responsible of violations guilty.

What has been the track record of action taken against the guilty? The non-implementation of the judgements makes acts like Drugs & Cosmetics Act a farce for the people, while loopholes continue to be used against the people by the vested interest.

Monitoring the number of drug related cases in the counts, in the past & at present, the action taken or not being taken & the time lag between the two, must be given high priority. These must be reported in the parliament, as regularly, as the budget announcement.

Exploitation in the name of medicine must stop.

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- Ref.** 1. Lentin Commission Report
2. JJ Deaths the Lentin Commission Report
3. Indian Express Rupa Chinai's coverage of the Lentin Case.
4. TOI 25.11.92
5. The Daily, Aug 12, 1991
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QUALITY CONTROL

WHO & Quality assurance

Quality assurance of drugs, as embodied in good manufacturing practice and subsequent monitoring of quality throughout the distribution chain to utilization, is a crucial element in any essential drugs programme. All aspects of these procedures have been dealt with at length in the twenty-sixth to thirty-first reports of the WHO Expert Committee on Specifications for Pharmaceutical Preparations.

Priority should be given to ensuring that the available drugs have been made according to good manufacturing practices and are of generally recognized quality. This requires knowledge of and confidence in the origin of the product. The risks of procuring drugs from anonymous sources cannot be overstressed. It is recommended that drugs are purchased directly from known manufactures, their duly accredited agents, or recognized international agencies known to apply high standards in selecting their suppliers.

Developing countries with inadequate laboratory facilities for drug analysis may be unable to carry out the process of quality control. In this connection, the Committee would emphasize the importance of WHO's certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. This has been available since 1975 as a means of exchanging information between regulatory authorities in importing and exporting countries. Its purpose are:

1. To provide assurance that a given product has been authorized to be placed on the market in the exporting country and, if not, to explain why authorization has been withheld.

2. To provide assurance that the plant in which the product is manufactured is subject to inspections at suitable intervals and conforms to the requirements for good practices in the manufacture and quality control of drugs, as recommended by WHO.

3. To provide for exchange of information on the implementation of inspections and controls by the authorities in the exporting country. In the case of serious quality defects inquiries may also be made.

In 1988 the scope of the certification scheme was extended, in accordance with World Health Assembly resolution WHA41.18, to provide for a more comprehensive exchange of information between governments. Drug substances as well as finished dosage forms were included within scheme and provision was made for the exchange of officially approved, product-specific prescribing information on the safety and efficacy of finished products.

The Committee wishes to encourage national authorities to issue certificates in precise conformity with the format proposed by WHO in order to ensure that clear details are given about a product's place of manufacture or assembly and whether WHO's standards of good manufacturing practice have been applied. Countries that have not already done so are urged to extend the system of licensing to manufactures of pharmaceutical products destined exclusively for export. The licensing system should ensure that these manufactures are subject to inspection, that they comply with internationally recognized requirements for good manufacturing practices, and that every reasonable precaution is taken to ensure that the quality of their products meets pharmacopoeial specifications.

Poor bioavailability is a particular problem for products of low solubility or narrow therapeutic index. It can result in adequate drug absorption and thus treatment

failure just as readily as products deficient in active ingredients. The bioavailability of essential drugs should continue to receive consideration since it is a key factor in quality assurance.

The Committee appreciates that the development of the Model List of Essential Drugs has provided a natural focus for the third edition of The International pharmacopoeia thus enhancing its potential value to developing countries. Essential drugs are accorded priority and all quality specifications are supported by classical methods of testing and analysis. A plan for a small quality-control laboratory in which most of these tests can be performed has been available since 1984. Since quality assurance of essential drugs is so important, the Committee recommends to national governments the setting up of such laboratories and the adoption of the international pharmacopoeia by those currently lacking the means to confirm independently the quality of the supplies they procure. In this context, attention is also drawn to the WHO publication Basic tests for pharmaceutical substances (20), which enables the identity of drug substances to be verified and gross degradation to be excluded when laboratory facilities for full pharmacopoeial analyses are not available.

The Committee emphasizes the need to extend the coverage of The international pharmacopoeia to include not only essential drug substances, but also the dosage forms specified in the Model List of essential Drugs, together with additional information on bioavailability, stability and recommended packaging and storage conditions.

QUALITY CONTROL IN MAHARASHTRA

In January 1986, in reply to a LAQ in the maharashtra assembly the health minister replied "there are 250 drug manufacturing units in the state that do not have their in-house quality testing laboratories. All these firms have been informed and their licences are not renewed". But under Section 72 of Drug & Cosmetics Act the companies continued to manufacture drugs and sell them - This was done as a policy matter decision. When this policy decision was taken the minister in charge issued licences to two of his friends and since then the practice continued. According to Mr.Bhirud, the minister, Dr.Lalita Rao was responsible.

How the ministerial interference spoilt the FDA is worth studying. The Gujarat FDA reported that Saynastrep of Sayna Pharma was found to be substandard. The Maharashtra FDA intelligence branch raided the company, but the health minister Bhai Sawant brought pressure on the FDA officials, not to take action against the defaulting firm. Naval Medico had stocked medicines without valid licenses and village uplift minister Mr.K M Bapu Patil and health minister Mr.V.Sarnaik brought pressure on the officials not to prosecute Naval Medico. Mr. R H Kaliya, FDA Supervisor himself was involved in the racket of illegally manufacturing Mandrax Tablets, when the then minister Satish Chaturvedi brought pressure on FDA officials to let go Mr.Kaliya scot free.

The FDA official is not allowed to go in pharmaceutical business - directly or indirectly, Mr.Dolas, the Joint Commissioner FDA has two of his daughters as partners in pharmaceutical units and his son was given a license to manufacture and sell drugs. All these examples go to prove how the ministers helped the corrupt FDA officials.

Mr. Bijamwar of FDA Maharashtra was in charge of public analytical laboratories. The drugs of the loan license firms were tested by these public analytical laboratories. He said there were 30 such laboratories and they were inspected only 10 times since 1984 to 1987. One of these Apex Laboratories had given false, incomplete, wrong and imaginary testing reports but no action was taken against them. The parenteral solution used in JJ Hospital was tested and passed by this laboratory. According to Mr.Bijamwar under Act 18C, 23 different offences could be lodged against this Laboratory, but they were penalised by giving 15 days suspension order.

Chem Med was another Laboratory that passed Batch No.27 of Glycerol of Alpana Pharma - They claimed that they did not examine the end product but only tested the chemicals that were used to prepare the solution. No action was taken against this Laboratory. Unique Pharmaceuticals Ifimycin and Curamycin were found substandard by government laboratories at Jammu and Kashmir, Calcutta and Madras, but Chem Med in Maharashtra had found it OK. The only

LAQ	: Legislative Assembly Question
FDA	: Food & Drug Administration
WHO	: Expert Committee on specification for pharmaceutical preparation
WHO's	: Certification scheme on Quality of Pharmaceutical products moving in International Commerce 1975 & 1988.

punishment given to this Laboratory was a warning to be more careful in the future.

Sayna Pharma had not only produced substandard Saynastrep, and Saynamycin but had also imitated the other company's products, for which they could have been penalised for 10 years imprisonment. But they were charged for only manufacturing substandard drugs for which 3 years imprisonment could have been given, and when this firm had committed such offences five times on the orders of the minister concerned he was allowed to go scot free.

Another FDA official was charged by Lok Ayukta and the strictures were ordered to be included in his confidential report but because of the then health minister Dr. Baliram Hire no action was taken against the official.

A circular issued by Dr. Prem Kumar Gupta, Drug Controller of India to his colleagues on 22nd April 1989 says: "The Drugs Control Organisation at the central and State levels.....is woefully inadequate to monitor the quality and regulate the production of safe drugs....." The same circular admits a serious lacuna in the country's drug control laws. "The act (Drugs and Cosmetics Act - 1940) empowers the government to prohibit manufacture, sale and distribution of a drug in public interest be directed to withdraw a drug from the market within a specific period...."

The Daily, Bombay, 26 May 1994 reports...."According to sources, the FDA staff in Thane used to take inordinate time in communicating to the manufacturers about the ban of drugs. As a result of this delay, manufacturers used to get enough time to dispose off the stock in the market by the time the ban order became effective".

In simple terms even if a drug proves to be contaminated or spurious, and even if it is known to be lethal, it can remain in the market for several long years before the government is finally able to take it off the shelves.

The Food and Drug Administration (FDA), Maharashtra had ordered (Jan.1992) Glaxo India Ltd., to close down its bulk drug factory at Thane and also its warehouse there for two days for violating drug manufacturing rules: the company was charged with manufacturing drugs without the presence of a technical person in three shift, not maintaining records that workmen are "free from infectious conditions" and not keeping storage area free of dust and cobwebs. The technical officer was also found to have signed the manufacturing record for the time when he was on leave.

Mr. Justice A.P. Shah of the Bombay High Court ordered Glaxo India Ltd. to comply "forthwith" with another order to close down its Worli factory for 10 days. This closure order was for violation of drug manufacturing rules pertaining to disposal of rejects - The FDA said these were being siphoned into the market for several years through the company scrap dealer, Baksull Setu alias Barkat Ali. This had happened even though Glaxo's officers had caught Ali walking away with rejects instead of destroying them in the presence of a technical officer (TOI 23 Jan.94).

It all started in 1992 during a raid on the premises of a scrap dealer Barkat Ali, when a bulk of rejected medicines, packaging materials and labels, both coded and uncoded of Glaxo were recovered. Revelations of further investigations shocked medical and pharmaceutical circles in the country. The scrap dealer confessed to selling the rejected

medicines to an enterprising Gujarati businessman operating from a Cubby hole in Ahmedabad (The Asian Age New Delhi 18 March '94).

On February 15, 1994, the Bombay High Court upheld the closure orders given by the F.D.A. The company opined "we feel we were being singled out although there were other pharmaceutical companies which were found to be violating the rules". This clearly shows the pathetic conditions of drug manufacturing in a state like Maharashtra and that too with multinational drug companies (Boots & German Remedies & Glaxo).

Mr.Arun Bhatia was instrumental in bringing these cases to limelight. In fact it seems this modus-operandi of the drug companies was going on for many years. It was only Mr.Arun Bhatia, an upright officer of the FDA, insisted on the act to be implemented. But he had to pay a price. He took over as FDA Commissioner on March 23, 1993 and he was made to hand over the charge on October 21, 1993. That establishes the nexus between the politicians and the drug manufacturers, so beautifully explained by Justice B.Lentin in Lentin Commission Report.

FDA, Maharashtra routinely publishes the withdrawn batches of drugs but who tries their early withdrawal from the market? On April 5, 1989 Ms Saroj Kharparde, then Minister of State for Health Welfare made a statement replying to a Parliament Question that only the States of Maharashtra, Gujarat, Karnataka and Tamil Nadu have facilities for testing all categories of drugs, while the States of Andhra Pradesh, Bihar, Madhya Pradesh, Orissa, Punjab, Uttar Pradesh, West Bengal, Rajasthan,

Haryana and Kerala have facilities for testing only non-biological products. The remaining States and Union Territories do not have any testing facilities..."

As on April 1, 1989, not a single State in India had the required number of drug inspectors.

State/UT	(April 1, 1989)		
	Required number of Drug Inspectors	Existing number of Drug Inspectors.	
Maharashtra	476	81	17%
Rajasthan	145	29	20%
Delhi	55	19	34%
Karnataka	105	86	82%
Gujarat	317	85	26.8%

Which clearly shows that the progressive state like Maharashtra has the most inadequate number of drug inspectors.

The regular, overworked personnel of the state drug authorities cannot be expected to make much headway in tasks like unearthing spurious drug rackets and efficiently pursuing matters on a legal level. There is an urgent need to constitute specially trained cells and to set up intelligence-cum-legal cells in each state drug control body for the purpose which has not been done so far.

When a certain drug or drug combination is banned, it is important to frame the gazette notificaiton so that it will not have any loophole and that it is complete in all respects.

Take the example of gazette notification item numbers 30 and 31; which read as follows:

No.30 Fixed dose combination (FDC) of

Histamin H2 receptor antagonists with antacids *except for those combinations approved by the Drug Controller of India.*

No.31 The patent or proprietary medicines of Fixed dose combinatio^s of essential oils with alcohol having percentage higher than 20% proof *except preparations given in Indian Pharmacopoeia.*

How is it possible for a consumer, doctor or a chemist to know *which FDC's the Drug Controller of India has approved* or which ones are given in Indian Pharmacopoeia?

In fact whenever a FDC is banned, the Drug Controller of India should publish the exhaustive list of brands falling under such a ban as was told by Justice Potti in his famous judgement of continued sales of hazardous drugs 1982. This alone can help the consumer. But unfortunately the Drug Controller of India does not have names of all the drugs and drug combinations registered with the various state authorities. It is thus essential that Central drug registration should be made compulsory.

Setting up of the National Drug Authority as provided in the New Drug Policy, 1994, is already long overdue. It must be set up immediately with the Health Ministry as the Nodal Ministry. Details about the role of NDA is given at in the end of the chapter.

At least those drugs banned by the Drug Controller of India, which continue to be sold because of the Court stay orders (against the ban orders) should be widely publicized by the Drug Controller of India. This can be done at the cost of the defaulting drug manufacturer.

Item No.40 - Preparations claiming to combat cough associated with asthma

containing centrally acting antitussive and/or antihistamine.

In this example a combination containing centrally acting antitussive and/or antihistamine prepared for treatment of dry cough cannot be used for treatment of cough associated with asthma. This is a glaring ambiguity and not practical to enforce. It should be made compulsory for the manufacturers to specify the use and indication and the wording of the gazette notification on the product label.

It was difficult for us to classify the products according to this ambiguous wording and there is a possibility that all as many of the anti-histamine and/or antitussive combinations might have been clubbed together.

Fake/Spurious Drugs Case - Lucknow, U.P.

On 15th April 1993 in Fatehpur and on 22nd April 1993 in Rae Bareilly, 16th April 1994 in Ferozabad, the drug control authorities found on drug testing of chloramphenicol capsules that there was no Chloramphenicol content in them , whatsoever, under the Drugs and Cosmetics Act 1940 the drug was declared spurious, The drug had been ironically sold to large number of Government hospitals in U.P.

These spurious drugs had been distributed by M/s Alok Trading

company, Badshahnagar Railway Station, Faizabad Road, Lucknow, which on investigation was found to be non existent.

The manufactures according to the label were Mac in Tosh Pharmaceuticals, Azadnagar, Madras. On investigation Director, FDA, Tamil Nadu the company was found to be non existent. Following a raid it was found that the

drugs were being manufactured by Drug India Company in Lucknow itself.

Several life saving drugs were also found to be spurious. Spurious drugs were being manufactured using the brand names of some essential and life saving drugs eg. Rifampicin an important anti TB drug, Cephalosporin an important antibiotics, Norflox, Salbutamol - anti asthmatic drug, etc.

On 21st January 1995 in Mahanagar Thana, Kamal Engineer Arora, a drug inspector had filed a case against Alok Trading company for manufacture of spurious drugs and use of fake license.

Several cases are pending in the courts and many of the manufacturers have been granted stay orders or their files have been closed, and the investigation slowed down due to interference and pressure from higher ups.

With support from a P.P.S. level government official and State Drug Control lab personnel an attempt to protect the culprit is being made.

Dr. Aggarwal has been actively pursuing this case of spurious drugs & police has been pursuing the matter.

In the meantime a circular and a public advertisement no. 20F/4444/2934 dt.18th March 1996 has been issued by Mr. K.C.Rastogi, State Drug Controller, from the office of the Director General of Health Services, U.P., making sales of Cosmetics, Food Supplements and Ayurvedic drugs from licensed chemist shops illegal. Their sales in chemist shop misguides the public into believing that these have medical value.

Yet the Cosmetics, Food Supplements and Ayurvedic drugs etc. continue to be sold and so

do the spurious drugs. What happens to this case is being keenly watched by Consumer and Health Groups.

Issues that emerge:

1. Need for strict monitoring of good manufacturing practice. G.M.P. strict standard adherence for those issued manufacturing licenses.
2. Strict monitoring of those issued drug sales license the name and photograph of the person should hang conspicuously in the chemist shop. Consumers must insist on examining it.
3. Adequate number of drug inspectors and government drug testing labs.
4. Setting up of Drug Courts to finish these cases at the earliest without granting stay orders, or letting the cases drag on with stringent punishment.
5. Quick stringent action against those selling spurious drugs.
6. Public exposure and stringent action against those government officials involved in covering up such nefarious activities and providing protection.
7. Demanding of accountability of politicians putting pressure on government officials to protect culprits.
8. Alertness on part of the consumers to look at the manufacturers name, license number, expiry date, clarity of the label and collection of the product as well as the cash memo.
9. Reporting to the concerned authority if doubtful about a drug being fake with a copy to us.

ANNEXURE 1

USEFUL ADDRESSES

DRUG CONTROLLERS, QUALITY CONTROL LABORATORIES

DRUG CONTROL ADMINISTRATIONS

Central Authorities

Under the Drug and Cosmetics Act, the regulation of manufacture, sale and distribution of drugs is primarily the concern of the State authorities while the central authorities are responsible for laying down the standards for drugs control over the quality of imported drugs, coordination of the activities of State Drug Control Organisations and supplying expert advice with a view to bring about the uniformity in the enforcement of the Drug and Cosmetics Act.

At the Centre, attached to the Directorate General of Health Services, at Nirman Bhawan, New Delhi-110 011. (Gram : HOSPITALS INDIA) is the Drug Controller of India, with one Deputy Drug Controller, two Assistant drug Controllers, one pharmacologist, one Biochemist, one Assistant Secretary (IPC), and four Technical Officers.

Drug Controller of India,
Phone Off 3018806.

Deputy Drug Controller, India
Phones Off 3017329

Deputy Drug Controller, India
(New Drugs)
Phones 3012192

Asstt. Drug Controller, India
Phone 3017329.

Central Authorities

Drug Controller of India
Nirman Bhawan
New Delhi-110 001
Gram: HOSPITALS INDIA
Tel : 3018806

Andaman & Nicobar Islands

Deputy Drug Controller of India
C.G.O.Bldg., (Nizam Palace)
2nd Floor
234/4 Lower Circular Road

Calcutta-700020

Gram: ZONDRUGS

Tel: 2470513

**Director of Health Services & Special Security
(Health)**

Andaman & Nicobar Islands

Port Blair - 744101

Gram : DIRMED

Tel: 21331.

Andhra Pradesh

Deputy Drug Controller of India

No/4, Aziz Mulk

7th Street, Thousands Lights,

Madras-600006

Gram: ZONEDRUG

Tel: 8278186.

**Director a/c Drug Control administration
Vengalraonagar**

Hyderabad-500890

Tel: 263563, 264360.

Assam

Director of Health Services Assam,

Hengrabari

Guwahati-781006

Tel: 87865, 87630

Bihar

State Drug Controller Bihar,

Drug Control Administration

Health Department

New Secretariate

Patna

Gram: HEALTH SERVICES

Tel: 221110

Dadra & Nagar Haveli

Chief Medical Officer

Silvasa 396230

Delhi

Drug Controller Delhi

15 Sham Nath Marg

Delhi 110054

Tel: 29992225359, 2517511

Goa

Director of Food & Drugs Administration

College Campus

PANAJI 403001

Tel: 224639

Gujarat

Commissioner of Food & Drug Administration

Ist Floor - 8th Block

Dr. Jivraj Mehta Bhawan

Gandhinagar

Tel: 20176, 21170 PABX 8261

**Asst.Commissioner Food & Drugs
Administration**

Block No.4, New Mental Hospital Compound

Asarwa

Ahmedabad 3800016

Tel: 379096

Asst.Comm. Food & Drugs Adm.

Room No.556 - 3rd Floor Multistoried

Bldg.

Nilam Bag Road

Bhawnagar

Tel: 29694

Haryana

State Drug Controller

Madhya Marg, Sector 7

Chandigarh 160019

Gram: MEDIRECTOR

Tel: 44255, 21231

Himachal Pradesh

State Drug Controller H.P.
SIMLA 171004
Gram: HIMHOSP
Tel: 3524

Jammu & Kashmir

Controller, Drug & Food Control Admn.
Patoli
Mangtorian
Jammu (J & K)
Tel - 4588, 49626

Karnataka

Drugs Controller - Karnataka
P.B.No.5377
Palace Road
Bangalore 560001
Tel: 2262846

Kerala

Drug Controller
Red Cross Road
Thiruvananthapuram 695037
Gram : DRUSTACOL
Tel: 73256, 71896

Madhya Pradesh

Controller, Food & Drug Administration
Idgah hills,
Bhopal
Tel: 72384, 73058

Maharashtra

Commissioner Food & Drug Administration
2nd Floor, Survey No.341
Bandra - Kurla Complex
Bandra East
MUMBAI 400051
Tel: 6422361/65. 6428848, 6427404
Deputy Drug Controller of India

C.G.H.S. Disp.Bldg.

1st Floor
Antop Hill
MUMBAI 400037
Gram : ZONDRUG
Tel : 485125

Manipur

Licensing & Controlling Authority
Directorate of Medical and Health Services
Manipur (Lamphel)
Imphal
Tel: 275768

Nagaland

Director of Health & Family Welfare
Ex-Officer Drug Controller
KOHIMA 797001
Tel: 2263.

Orissa

Drug Controller
Nandankanam Road
Bhubaneswar 751017
Tel: 51694.

Pondicherry

Commissioner Food & Drug Administration
Pondicherry Post Box No.50
605001
Tel: 37050

Punjab

State Drug Controller
SCO 459-60
Sector 35-C
Chandigarh 160026
Gram : ST 1263
Tel: 4533611
Deputy Drug Controller of India
C.G.O. Bldg.,

Kamala Nehru Nagar
Hapur Road - Chungi
Ghaziabad - 201002
Gram: ZONDRUG
Tel : 8-719483.

Rajasthan
Drug Controller
Jaipur
Gram : RAJMEDICAL
Tel : 381858

Tamilnadu
Director Drug Control
259-261, Anna Salai
Madras- 600006
Tel: 454130.

Tripura
Deputy Drug-Controller
Assaf Rifles Office Complex
Kungaban 799006
Tel: 5844.

Uttar Pradesh
Drug Controller
Swasthya Bhawan
Lucknow.

West Bengal
Director of Drug Control

College Square West
Calcutta-700073
Gram: CALDRUG
Tel: 323324, 323388, 3223391, 321172.

QUALITY CONTROL LABORATORIES

Director,
Central Drugs Laboratory,
3-Kyd street,
Calcutta - 700016

Director,
Central Research Institute,
Kasauli (H.P.).

Director,
Indian Veterinary Research,
Institute, Izatnagar (Near Bareilly),

Director,
Central Drugs Research Institute,
Chattar Manzil,
Lucknow.

The Director,
Central Indian Pharmacopoeia,
Laboratory Raj Nagar,
Ghaziabad - 201002.

ANNEXURE 2

FURTHER INFORMATION

Material prepared by VHAI, AIDAN & other groups

THE INDIAN DRUG SCENE

1. The Drug Situation in India	1982	VHAI
2. A Study of Prevalent Diseases in India and Production of Some Essential Drugs	1982	FMRAI
3. Community Health Needs and India's Drug Industry	1984	JNU
4. Drugs As if People Mattered: Special edition of Health for the Millions	(1981 April/June)	VHAI
5. People Vs Profits : Health for the Millions	1986	VHAI

HAZARDOUS DRUGS

1. Hazardous, banned, bannable and dumped drugs	1984	VHAI
2. The Clioquinol Controversy	1982	VHAI
3. Anti-diarrhoeals: Focus on Clioquinol	1983	VHAI
4. Why amidopyrines (including analgin) must go	1982	VHAI
5. Some painful facts about a painkiller called amidopyrine	1983	VHAI
6. Using tetracycline for children and pregnant women	1982	VHAI
7. Anabolic steroids	1982	VHAI
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9. Oxyphenbutazone-Phenylbutazone	1984	VHAI
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11. Misuse of antibiotics	1984	VHAI
12. Selection of appropriate analgesic and anti-inflammatory drugs	1984	VHAI

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a. Are hormonal pregnancy tests safe?	1982	MFC
b. Dear Sister letter for the EP Campaign	1982	VHAI
c. References on Oestrogen-Progesterone test for Pregnancy	1982	VHAI
d. Dear Doctor/Chemist letter	1982	VHAI
e. Review of supportive hormone therapy in Obstetrics	1982	VHAI
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14. Hazardous Drugs Booklet	1989	MFC & AIDAN
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3. Fixed-dose combinations of steroids	1984	AIDAN
4. Anti-diarrhoeal formulations: a rationality study	1985	MFC
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ESSENTIAL DRUGS

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1. Seeking information regarding anti-TB drug shortages	1982	VHAI

2. Rational TB Care - A priority	1983	VHAI
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4. The BCG story	1984	
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7. Drug production for a National Priority Programme -TB	1985	VHAI
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AMNIOCENTESIS - for sex determination

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2. Some instances of drug dumping	1982	VHAI
3. Drugs and Magic Remedies Act	1984	CERC
4. Drugs and Cosmetics Act - Updating necessary	1983	VHAI
5. Pharmacy Act	1983	VHAI
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7. A note on the legal aspects of health issues and VHAI's intervention	1983	VHAI

RATIONAL DRUG POLICY

1. People Oriented Drug Policy - Mozambique	1983	VHAI
2. Memorandum : Demand for A Rational Drug Policy for India	1983	VHAI
3. Memorandum for a National Drug Policy	1983	AIDAN
4. Towards an Alternative Drug Policy - some criteria	1984	FMRAI
5. Criteria of Rational Drug Policy	1984	DAF WB
6. AIDAN Working Group Response to Steering Committee Recommendations	1984	AIDAN
7. Drug Pricing & Pricing Policy	1984	ADM
8. AIDAN's Rational Drug Policy Statement	1985	VHAI
9. Rational Drug Policy Kit	1986	VHAI
10. Rational Drug Policy (Problems and Recommendations)	1986	AIDAN
11. Drugs as if people mattered, Medical Service	1986	CHAI
12. Critique of the National Health Policy	1987	VHAI
13. Critique of the New Drug Policy	1986	VHAI
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15. National Drug Policy - Submission to the Parliament	1994	VHAI, NCCDP
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RATIONAL DRUG ECONOMY

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2. Medicines Procurement and Stock Control		
Purchase of Medicines	1984	CMAI
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5. Experience of a 'Hospital Pharmacy'	1982	VHAI
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3. What consumers can do	1983	VHAI
4. Drug information for consumer		CC
5. Inadequate information on OTC Analgesic drugs	1983	CERC

LEGAL ACTION

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2. Amendment of the above public writ petition		PLC
3. Net-en submission (long acting injectable contraceptive)		SAHELI
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		VHAI &
		AIDAN
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		DAFK
		AIDAN-
		NCCDP
		LOCOST,
		CDMU

- | | | |
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writ petition No. (C) No 698 of 1993 | 1993 | |
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BANGLADESH DRUG POLICY

- | | | |
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| 2. Drug Control Ordinance Promulgated | 1982 | VHAI |
| 3. The Bangladesh ban on hazardous and irrational
drugs, its review and present status | 1982 | VHAI |
| 4. National Drug Policy for Bangladesh, from
Expert Committee Report | 1982 | VHAI |
| 5. Bangladesh War - Part I and Part II | 1982 | VHAI |
| 6. Bangladesh : Finding the right prescription
(special edition of Health for Millions) | 1982 | VHAI |
| 7. Essential Drugs for the Poor - a myth a reality | 1982 | GK |
| 8. Gonoshasthya Kendra - People's Health Center | 1983 | VHAI |
| 9. A courageous Drug Policy - The Bangladesh example | 1986 | VHAI |
| 10. Bangladesh Drug Policy - 4 years on | 1987 | IOCU |
| 11. Bangladesh Drug Policy | 1993 | IOCU |
| 12. The politics of Essential Drugs | 1996 | Dr. Zafarullah
Chowdhury
Gonosasthya
Kendra |

CONSUMER ALERTS

- | | | |
|--|------|------|
| 1. Clioquinol - withdrawal of Mexaform | 1984 | VHAI |
| 2. Oxyphenbutazone and Phenylbutazone - withdrawal
of Tanderil | 1984 | VHAI |
| 3. U.S.Bill to allow exports of hazardous drugs | 1984 | VHAI |
| 4. Re-entry of Hatch Bill (U.S.A.) to allow
export of hazardous drugs | 1985 | VHAI |
| 5. U.N. consolidated list - exclusion of brand names | 1985 | VHAI |
| 6. J.J.Deaths | 1988 | VHAI |

HEALTH CAMPAIGNERS

- | | | |
|--|------|------|
| 1. Dr. Olle Hansson - Biodata | | VHAI |
| 2. Dr. Olle Hansson - The Passing away of a health
campaigner | 1985 | VHAI |
| 3. Dr. Andrew Herxheimer - | 1985 | VHAI |
| 4. Dr. Zafarullah Chowdhury - Biodata | 1982 | VHAI |

VHAI AND THE DRUGS ISSUE

- | | | |
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Note : Most of the above have been prepared as cyclostyled handouts to keep costs low - some of the important ones are being updated and will be available at cost price in printed form.

DRUGS IN INDIA

- | | | |
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industry in India | 1982 | Mukarram Bhagat
CED Bombay |
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An Alternative Strategy | 1981 | ICSSR & ICMR study
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| 4. The Indian Pharmaceutical
Industry: Problem and prospects | 1984 | P.L. Narayan (NCAER) |
| 5. Statement of National
Health Policy | 1983 | Ministry of Health
Govt. of India |
| 6. Multi-Nationals and the
Pharmaceutical Industry in India. | 1985 | KSSP |
| 7. Drugs for the people or
people for the drugs
(Bengali & Hindi) | 1985 | DAF WB |
| 8. List of Banned Drugs (Bengali) | 1985 | DAFWB |
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| 10. Issues in the Drug Policy
Group | 1987 | Pondicherry Science |
| 11. A Decade After Hathi Committee | 1988 | KSSP |
| 12. CDMU Drug information | 1988 | CDMU |
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Medical Education | 1992 | ERDU |

ON INTERNATIONAL CODES

International Federation of Pharmaceutical Manufactureres Association (IFPMA, 1982)
International Codes & You (VHAI, 1984)

Ethical Criteria for Marketing of Pharmaceuticals.

NATIONAL LEGISLATION

Drugs & Cosmetics Act 1940

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ERDU — Educators for Rational Drug Use.

ON HEALTH AND DRUGS

1. In Search of Diagnosis	MFC	1977
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3. Where There is No Doctor	VHAI	1980, 1988, 1994
4. Private Sector Privatization in the Health Sector	FRCH	1993
5. Rakku's Story	Centre for Social Action	1988
6. Health Situation in India	Centre for Social Action	1990
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REPORTS

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5. International Consultation of WHO Experts on Rational Drug Use. Nairobi	WHO	1985
6. Drugging of Asia, Pharmaceuticals and the Third World Madras	VHAI-ACH-AN IOCU	1985
7. Drug Industry & the Indian People, Delhi	DSF-FMRAI	1986
8. National Drug Policy Seminar, Delhi	IMA	1987
9. Kelkar Committee Report	VHAI	1987
10. DPCO 1986		1987
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12. Essential Drugs in Primary Health Care, Delhi.	NIPCCD	1988
13. Rational Drug Use in Paediatrics, Delhi	AIIMS	1988
14. National Seminar on Patent Laws	Delhi National Working Groups on Patent Laws	1988
15. Modifications in Drug Policy		1994
16. DPCO 1994	G.O.I.	1995

GENERAL BOOKS

Name of the Book	Writer	Publisher	Year
1. Insult or Injury?	Charles Medawar	Social Audit	1980
2. Bitter Pills	Dianna Melrose	Oxfam	1982
		Public Affairs Unit	
3. Drugs & the Third World	Anil Agarwal	Earthscan	1978
4. There is Gold in them Thar Pills	Alan Klass	Penguin Special	1975

5. Poor Health, Rich Profits	Tom Heller	Sokesman Books	1977
6. Limits to Medicine— medical nemesis	Ivan Illich	Pelican Books	1980
7. The Health of Nations: A north south investigation	Mike Mullar	Faver & Faver Ltd.	1982
8. Pills against Poverty	Goran Djurfeldt Col. Staffan Linelbery	Oxford IBH Pub New Delhi	1976
9. Drugging of Americas	Milton Silverman	Berkeley University of California press	1974
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11. Drug Disinformation	Charles Medawar	Social Audit, London	1980
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16. Drug-induced Sufferings (Proceedings of the Kyoto Conference)	Sode T.	Excerpta Medica	1980
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29. Essential Drugs & Developing countires	Mesuma Mamdani Godfrey Walker	Evaluation & Planning centre for Health Care London School of Hygiene & Tropical Medicine	1984
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31. Rational Drug Policy	Ed. Mira Shiva	AIDAN	1986
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Fluids Sur a Tragedy	Unnikrishnan	VHAI	
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		1009 AB Amsterdam Netherlands	
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Reference books on drugs

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New York, NY 110017, USA.
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1985

James W.Long: Harper and Row Publishers, New York

6. Textbook of Adverse Drug Reactions

Second Ed.
Davies D.M. Oxford University Press, New York, Toronto.

1981

PERIODICALS

Sources of people-oriented drug information

1. Drug Information Bulletin

WHO, 1211 Geneva 27,
Switzerland

2. The Medical Letter on Drugs and Therapeutics

56, Rechell, New York, USA 10801

3. Drugs & Therapeutics Buletin

Consumers Association, 14, Buckingham Street, London, WC2 UK.

4. HAI News - Health Action International

Consumer International, PO Box 1045, Penang, Malaysia.

5. The Rational Health

Rational Health, Oxfam, 274,Campaign Newsletter Banbury Road, Oxford OX2 7D2,(Private circulation) UK.

6. Consumer Currents.

IOCU, P.O. Box 1045.

7. Consumer Interpol

Penang, Malaysia
IOCU, P.O. Box 1045
Penang, Malaysia.

8. Contact (free)
Special issue on drugs

Christian Medical Commission, World Council of Churches, 150 Route de Ferney, 1211 Geneva, 20 Switzerland

9. Pune Journal of Continuing Health Education (old issues)

Arogya Dakshata Mandal 1913 Sadashiv Peth, Pune 30

10. Medico Friend Circle Bulletin

MFC 50 LIC Quarters University Road, Pune
LOCOST GPO BOX 134

11. LOCOST Newsletter

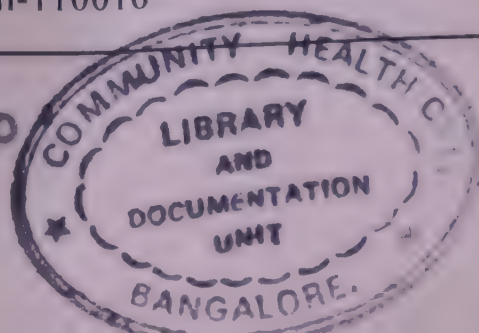
Baroda 3909 001

12. Health For the Millions
VHAI

40 Institutional Area
South of IIT (Near Qutab Hotel),
New Delhi-110016

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DR-410
N96
03990



- | | |
|---|--|
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4, Battery Street,
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PGI of Medical Education
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of India 157/6 Staff Road
P.Box 2126
Secunderabad-500003 A.P. |
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60A, Pali Road, Bandra (West)
Bombay-400050 |
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85, Marylebone High Street |
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Christian Medical Association
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Shotley Bridge General
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Consett. County Durham,
DH8 ONB U.K. |
| 19. Drug, Disease & Doctor | Drug Action Forum (West
Bengal) 254 Block B
Lake Town, Calcutta 700089. |
| 20. Essential Disease Monitor | WHO, 1211 Geneva 27
Switzerland |
| 21. Central Council for Research
in Unani Newsletter | 5 Panchsheel shopping
Center, New Delhi 110017 |
| 22. Development Dialogue,
Another Development in
Pharmaceuticals & National Drug
Policy (1985, 1995) | Dag Hammerskjold
Foundation, Dag
Hammarskjold Center
Ovre Slottsgatan 2, S-752
20 Uppsala, Sweden. |
| 23. MALAM
Medical Lobby for Appropriate
Marketing | MALAM 22, Renaissance Arc
Adelaide SA 500 Australia |
| 24. Current Highlights
(R & D) | National Information
For Drugs & Pharmaceuticals (NICDAP) |
| 25. Drug Industry | WHO Collaborating Center on
Drug Information |

26. Industry Highlights (R&D)

27. AIDAN newsletter

28. BODHI

29. Prescriber Int.

30. Dear Doctor

31. Hello Doctor here is a challenge

Central Drug Research
Initute, P.O. Box No.173
Lucknow 226 001

CDRI

All India Drug Action
Network, VHA1

254 Lake Town

Calcutta-700089

BP459-75527 Paris Cedex-II, France

Rajasthan VHA, C-80 Ramdas Marg,

Tilak Nagar, Jaipur-302004

VHA1

SOURCES OF COMMERCIAL DRUG INFORMATION

1. Eastern Pharmacist Independent
Organ of Pharmaceutical Industry
trade and profession

2. Monthly Index of Medical
Specialities (MIMS)

3. Current Index of Medical
Specialities (CIMS)

4. IDMA Bulletin

5. Drug Today

7. Express Pharma Pulse

8. Drug Today

9. Indian Pharmaceutical Guide

507, Ashok Bhawan

93, Nehru place

New Delhi-110 019.

90, Nehru place

New Delhi-110 019

Biogard Medical Services

640, 10-A Cross

West of Chord Road

(II Stage)

Bangalore 560 086.

Indian Drug Manufacturers,

102 B Poonam Chambers,

Dr. A.B. Road, Worli,

Bombay-400 018.

1, Mother Dairy

Commercial Complex

Mayur Vihar Packet-1

Phase-1

Delhi-110 091.

Indian Express

Nariman Point,

Bombay-400021.

1, Pocket-1, Commercial Complex

Mayur Vihar Phase I, New Delhi-110091

Pamposh Publications, 506-Ashok Bhavan

93, Nehru Place, New Delhi-110019

POSTERS

- | | |
|--|-------------------------------|
| 1. Drugs for the People or People for the Drug | DAF |
| 2. Profits before people | VHAI |
| 3. Murder in the name of Medicine | VHAI |
| 4. Don't judge a medicine by its packaging | VHAI |
| 5. Ban Bannable Drugs | VHAI |
| 6. Drugs can be dangerous too | VHAI |
| 7. Drug Posters | WBVHA |
| 8. Set of T.B. Posters | VHAI |
| 9. Drug Posters Medicines & Children | Indian Academy of Paediatrics |

VIDEO FILMS ON DRUGS

- | | |
|--|------------------------|
| 1. In the Name of Medicine | Media Collective |
| 2. Pills, Policies, Profits | VHAI |
| 3. Anatomy of a Ban : EP drugs | Doordarshan/Chitrabani |
| 4. Banned drugs | Inter News |
| 5. Rog Purana | DSF |
| 6. Bangladesh finds the Right Prescription | Gonoshasthya Kendra |
| 7. The Pill Jungle | WHO |
| 8. Healthy Business | German T.V. |
| 9. Hard to Swallow | Oxfam |

GLOSSARY

Agranulocytosis	A blood disease (often fatal) in which the bone marrow fails to produce white blood cells which fight infection and are essential to life, so that patient easily succumbs to infection and can die.
Allopathy	Western 'modern' medicine.
Analgesic	Drug which reduces pain.
Antagonism	Drugs working against each other in the body.
Antiphlogeslic	An agent Counter acting inflammation & fever.
Anti-pyretic	Drug which reduces fever.
Brand name	The trade name given to a drug by its manufacturer.
Contra-indication	Conditions under which a drug should never be taken
Generic name	The accepted scientific name of a drug which is also the non proprietary name or the pharmacopeal name (not the brand name).
Indication	Recognised illnesses or symptoms for which a drug should be used.
Inflammation	Local swelling of a joint mainly due to accumulation of uric acid etc. Inflammation of a viscera (eg. uterus) by various causes, for example infection.
Oral Rehydration Solution	2 finger pinch of salt in one glass of water - no more saltier than tears and one teaspoon (or a single four finger scoop of sugar).
Osseous	Bony.
Over-the-counter drugs (OTC)	Drugs which can legally be purchased without a prescription.
Resistance	Resistance to a drug has occurred when it is no longer effective. This can be either because the drug has been unnecessarily used earlier for trivial illness or because the drug ha been given for the correct disease but not in sufficient quantities or for long enough period to kill the germs completely, so that the germs survive in

a form which is immune (resistant) to that drug.

Steroids

Steroids are a group of biologically active compounds which are mainly divided into two categories i.e. HORMONAL STEROIDS and NON-HORMONAL STEROIDS. Hormonal Steroids include a great number of pharmaceutical preparations such as : sex steroids for example ANDROGENS or male sex hormones (testosterone and anabolic steroids). ESTROGENS or female ovulatory hormones (estradiol). PROGESTROGEN or female luteal hormone (Progesterone). Non-sex hormones include GLUCOCORTICOIDS (such as Cortisone & Cortisole betamethazone, dexamethazone), and MINERALOCORTICOIDS (such as aldosterone, desoxycorticosterone). Among the non-hormonal steroids, are Sterols, bile etc.

Sub-therapeutic dose

An amount of medicine too small to have an effect.

Therapeutic dose

The amount of medicine that is required for it to have the desired effect

Titration

To quantify using chemical methods

Toxic

Harmful to the body.

ERRATA

1. E-mail-VHAI @ UNV.ERNET.in
2. In forward by - Dr.Balasubramaniam in 2nd last para 'bringing' instead of 'bring'
3. Page 17, 3rd para, last line - the word 'for' should be 'or'
4. Page 18, 8th para, 2nd last line - 'and' should not be there it should be 'Liberalization without Rationalisation'
5. Page 28, 3rd para, 1st line - word 'come' is missing and also 'are'
6. Page 30, No.1 - 'with' instead of 'in'
7. Page 30, No.9 - 'of' instead of 'if'
8. Page 31, No.7 - 'INH' instead of 'IN'
9. Page 44, 1st para - the spelling is 'PANCYTOPENIA'
10. Page 74, last para, 2nd last line - the word 'use' is missing after 'intravenous'
11. Page 76, 1st para, 4th line - The line is 'The potency of propoxyphene hydrochloride is half to 2/3 that of codein given orally'
12. Page 81, 3rd para - The spelling is 'Justification'
13. Page 83, 1st para, last time - 'and' should not be there before 'ureamia'
14. Page 87, 6th para, last time - spelling of 'pill'
15. Page 90, 1st line - (,) after hazardous
16. Page 91, 1st para, last line - the word is 'with' instead of 'in' after strychnine
17. Page 98, 2nd para of 'The Gazette of India' - wrong spelling of 'cosmetics'
18. Page 99, 1st para, 12th line - The word is 'while' instead of 'white'
19. Page 99, 2nd para, last line - the word 'two' should not be there
20. Page 99, last para, 1st line - A full stop after banned
21. Page 104, last para, 6th line - 'medicine' instead of 'machine'
22. Page 106, last para - 'c' is missing in word influence, word 'and' is missing after 'tests' and a fullshop after 'policy'
23. Page 110, 2nd para - The sentence is 'flip sides of the same coin'
24. Page 110, 3rd para - The spelling is 'preparation'
25. Page 128, last para, 1st line - The word is 'court' instead of 'count'
26. Page 131, 2nd para, last line - 'go' should come after 'Mr.Kaliya' not before

ERRATA

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Where the mind is without fear
and the head is held high;
where the knowledge is free;
Where the world has not been broken up
into fragments by narrow domestic walls;
Where the words come out from the depth of truth;
Where tireless striving stretches its arms
towards perfection;
Where the clear stream of reason
has not lost its way into the dreary desert sand
of dead habit;
Where the mind is lead forward
by thee into ever-widening thought and action
Into that heaven of freedom,
my Father, let my country awake.

— *Rabindranath Tagore*

RATIONAL DRUG POLICY FOR RATIONAL DRUG USE : OUR MAIN DEMANDS

- Formulation of a Rational Drug policy based on the Concept of essential Drugs to be applicable both for public & private sector.
- Availability of essential and life saving drugs
- Withdrawal of hazardous and irrational drugs
- Availability of unbiased drug information
- Adequate quality control and drug control
- Affordable drug prices.
- Drug legislation reforms
- Use of generic names
- Technological self reliance



VHAI



AIDAN